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Casirivimab/Imdevimab (Ronapreve®)

Roche Pharma AG

Anhang 4-G zu Modul 4 B

Behandlung einer COVID-19 bei Erwachsenen und Jugendlichen, die keine zusätzliche Sauerstofftherapie benötigen und bei denen ein erhöhtes Risiko für einen schweren Verlauf von COVID-19 besteht

Stand: 14.04.2022

Datenschnitt 18.02.2021 (DCO1)

Übersicht:

Studie COV-2067

Datenschnitt: 18.02.2021 (DCO1)

Wirksamkeit	
Hauptdokumente	
t12-1-eff-resp-strat-tthos	Hospitalization or all-cause death by day 29
t12-1-eff-resp-unstrat-tthos	Hospitalization or all-cause death by day 29 (subgroup)
t12-2-eff-resp-strat-dth29	All-cause death at Day 29
t12-2-eff-resp-unstrat-dth29	All-cause death at Day 29 (subgroup)
t12-3-eff-resp-strat-dth169	All-cause death at Day 169
t12-3-eff-resp-unstrat-dth169	All-cause death at Day 169 (subgroup)
t12-4-eff-resp-strat-tthos2	Hospitalization or all-cause death from day 4 through day 29
t12-4-eff-resp-unstrat-tthos2	Hospitalization or all-cause death from day 4 through day 29 (subgroup)
t12-5-eff-resp-strat-tthcvd	Hospitalization or ER visit or all-cause death through day 29
t12-5-eff-resp-unstrat-tthcvd	Hospitalization or ER visit or all-cause death through day 29 (subgroup)
t12-6-eff-resp-strat-hosp	Hospitalization through day 29
t12-6-eff-resp-unstrat-hosp	Hospitalization through day 29 (subgroup)
t12-7-eff-resp-strat-er	ER visit through day 29
t12-7-eff-resp-unstrat-er	ER visit through day 29(subgroup)
t12-8-eff-resp-strat-mecvent	Mechanical ventilation through day 29
t12-8-eff-resp-unstrat-mecvent	Mechanical ventilation through day 29 (subgroup)
t12-9-eff-resp-strat-oxysup	Supplemental oxygen through day 29
t12-9-eff-resp-unstrat-oxysup	Supplemental oxygen through day 29 (subgroup)
t12-10-eff-resp-strat-icu	Admission to ICU through day 29
t12-10-eff-resp-unstrat-icu	Admission to ICU through day 29 (subgroup)
f1-1-km-plot-overall-tsres	Time to COVID-19 symptoms resolution
t13-1-eff-tte-strat-tsres	Time to COVID-19 symptoms resolution
t14-5-eff-mean-overall-sec19	Time to COVID-19 symptoms resolution
f1-1-km-plot-subgrp-tsres	Time to COVID-19 symptoms resolution
t13-1-eff-tte-unstrat-tsres	Time to COVID-19 symptoms resolution (subgroup)
PRO	
t14-2-eff-mean-overall-eq5d0206-eq5dbl	EQ-5D-5L VAS
t15-eff-mmrn-overall-eq5d0206	EQ-5D-5L VAS
f2-2-mean-plot-overall-eq5d0206-eq5dbl	Figure 2.2. Line plot of mean of EQ5D02-EQ VAS Score at each visit Modified Full Analysis Set
t14-3-eff-mean-overall-preco19h	Return to usual health
t14-4-eff-mean-overall-preco19a	Return to usual activities
f1-2-km-plot-overall-ttdet10	EQ-5D-5L VAS/ MID = 10: time to first deterioration
t13-2-eff-tte-strat-ttdet10	EQ-5D-5L VAS/ MID = 10: time to first deterioration
f1-3-km-plot-overall-ttdets10	EQ-5D-5L VAS/ MID = 10: time to first deterioration - Sensitivity Analysis
t13-3-eff-tte-strat-ttdets10	EQ-5D-5L VAS/ MID = 10: time to first deterioration- Sensitivity Analysis
f1-4-km-plot-overall-ttimp10	EQ-5D-5L VAS/ MID = 10: time to first improvement
t13-4-eff-tte-strat-ttimp10	EQ-5D-5L VAS/ MID = 10: time to first improvement
f1-5-km-plot-overall-ttdet15	EQ-5D-5L VAS/ MID = 15: time to first deterioration
t13-5-eff-tte-strat-ttdet15	EQ-5D-5L VAS/ MID = 15: time to first deterioration
f1-5-km-plot-subgrp-ttdet15	EQ-5D-5L VAS/ MID = 15: time to first deterioration
t13-5-eff-tte-unstrat-ttdet15	EQ-5D-5L VAS/ MID = 15: time to first deterioration (subgroup)
f1-6-km-plot-overall-ttdets15	EQ-5D-5L VAS/ MID = 15: time to first deterioration - Sensitivity Analysis
t13-6-eff-tte-strat-ttdets15	EQ-5D-5L VAS/ MID = 15: time to first deterioration - Sensitivity Analysis
f1-7-km-plot-overall-ttimp15	EQ-5D-5L VAS/ MID = 15: time to first improvement
t13-7-eff-tte-strat-ttimp15	EQ-5D-5L VAS/ MID = 15: time to first improvement
f1-7-km-plot-subgrp-ttimp15	EQ-5D-5L VAS/ MID = 15: time to first improvement
t13-7-eff-tte-unstrat-ttimp15	EQ-5D-5L VAS/ MID = 10: time to first improvement (subgroup)
f1-8-km-plot-overall-ttrtuh	Return to usual health: Time to 'Yes'
t13-8-eff-tte-strat-ttrtuh	Return to usual health: Time to 'Yes'
f1-8-km-plot-subgrp-ttrtuh	Return to usual health: Time to 'Yes'
t13-8-eff-tte-unstrat-ttrtuh	Return to usual health: Time to 'Yes' (subgroup)
f1-9-km-plot-overall-ttrtua	Return to usual activities: Time to 'Yes'
t13-9-eff-tte-strat-ttrtua	Return to usual activities: Time to 'Yes'
f1-9-km-plot-subgrp-ttrtua	Return to usual activities: Time to 'Yes'
t13-9-eff-tte-unstrat-ttrtua	Return to usual activities: Time to 'Yes' (subgroup)
Ergänzende Dokumente	
t1-dstat-subgrp_mfas	Number of patients for each subgroup and category per arm Modified Full Analysis Set
t3-center_mfas	Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm (mFAS Population)

t4-dstat-demo	Demographic and Baseline Characteristics per arm
t5_disposition	Table 5.1. Summary of Overall Patient Disposition
t5_screen	Table 5.2. Number of screened patients and reason for screening failure
t2-dstat-dur_mfas	Duration of Follow-up by domain and arm Modified Full Analysis Set
t21_1	Table 21.1. Concomitant medications day 1 to day 29
t21_2	Table 21.2. Concomitant medications day 1 to day 29 Indication Reason: Treatment of Adverse Even
t21_3	Table 21.3. Concomitant medications day 1 to day 29 Indication Reason: Medical History
t21_4	Table 21.4. Concomitant medications day 1 to day 29 Indication Reason: Other
t21_5	Table 21.5. Concomitant medications day 1 to day 29 Indication Reason: Premedication
t22_1	Table 22.1. Concomitant procedures day 1 to day 29
t22_2	Table 22.2. Concomitant procedures day 1 to day 29 Indication Reason: Medical History
t22_3	Table 22.3. Concomitant procedures day 1 to day 29 Indication Reason: Adverse Event
t22_4	Table 22.4. Concomitant procedures day 1 to day 29 Indication Reason: Disease under study
t22_5	Table 22.5. Concomitant procedures day 1 to day 29 Indication Reason: Other
CSR_2067_Tab27_p56_risk_factors	Table 27: Frequency of Baseline Risk Factors for Severe COVID-19 (Phase 3, mFAS)
Executive_Summary_PRO_Dossier	
Verträglichkeit	
Hauptdokumente	
t18-1-ae-raw-anyae-saf1	Any AEs
t18-2-ae-raw-anyae-r-saf1	Any AEs (excluding disease related events)
t18-3-ae-raw-toxgrgt3-saf1	AEs Grade >= 3
t18-4-ae-raw-toxgr3-saf1	AEs Grade >=3 (excluding disease related events)
t18-5-ae-raw-toxgr4-saf1	AEs Grade 3
t18-6-ae-raw-toxgr5-saf1	AEs Grade 4
t18-7-ae-raw-toxgr6-saf1	AEs Grade 5 (AEs leading to death)
t18-8-ae-raw-anysae-saf1	Any SAEs
t18-9-ae-raw-anysae-r-saf1	Any SAEs (excluding disease related events)
t18-10-ae-raw-aeldis-saf1	AEs leading to treatment discontinuation
AESI	
t18-11-ae-raw-irr-saf1	IRRs through day 4
t18-12-ae-raw-irrg3-saf1	Grade >= 3 IRRs through day 4
t18-13-ae-raw-sirr-saf1	Serious IRRs through day 4
t18-14-ae-raw-hyp-saf1	Hypersensitivity through day 29
t18-15-ae-raw-hypg3-saf1	Grade >= 3 Hypersensitivity through day 29
t18-16-ae-raw-shyp-saf1	Serious Hypersensitivity through day 29
SOC/PT	
t19-1f-ae-raw-soc-anyae-fs-saf1	Any AEs
t19-2f-ae-raw-soc-anyae-r-fs-saf1	Any AEs (excluding disease related events)
t19-3f-ae-raw-soc-toxgrgt3-fs-saf1	AEs Grade >= 3
t19-4f-ae-raw-soc-toxgrgt3x-fs-saf1	AEs Grade >= 3 (excluding disease related events)
t19-5f-ae-raw-soc-toxgr3-fs-saf1	AEs Grade 3
t19-6f-ae-raw-soc-toxgr4-fs-saf1	AEs Grade 4
t19-7f-ae-raw-soc-toxgr5-fs-saf1	AEs Grade 5
t19-8f-ae-raw-soc-anysae-fs-saf1	Any SAEs
t19-9f-ae-raw-soc-anysae-r-fs-saf1	Any SAEs (excluding disease related events)
t20-1-ae-soc-descriptive-trtdc-saf1	AEs leading to treatment discontinuation
Outcome	
t17-ae-resolved-aesi	Resolved AESI
t16-ae-resolved-general	AE resolved general
Ergänzende Dokumente	
t2-dstat-dur_saf	Duration of Follow-up by domain and arm Safety Analysis Set

Datenschnitt 18.02.2021 (DCO1)

Wirksamkeit

Hauptdokumente

POPULATION: mFAS
 ENDPOINT: Hospitalization or all-cause death by day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value	Interaction Test p-value (Relative Risk)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	736	100.0	7	1.0	748	100.0	24	3.2	0.29	Algorithm converged.	0.12	0.68	-2.257	Algorithm converged.	-3.70	-0.81	0.30	Algorithm converged.	0.13	0.68	0.0024		3.37	Algorithm converged.	1.46	7.78

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binaryl-excel.sas
 Output: t12-1-eff-resp-strat-tthos.xlsx, t12-1-eff-resp-strat-tthos.pdf

POPULATION: mFAS
 ENDPOINT: Hospitalization or all-cause death by day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroups
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	7	1,0	748	100,0	24	3,2	0.29	Algorithm converged.	0.12	0.68	-2.257	Algorithm converged.	-3.70	-0.81	0.30	Algorithm converged.	0.13	0.68	0.0024		3.37	Algorithm converged.	1.46	7.78
Sex	Male	364	49,5	5	1,4	352	47,1	14	4,0	0.34	Algorithm converged.	0.12	0.94	-2.604	Algorithm converged.	-4.97	-0.24	0.35	Algorithm converged.	0.13	0.95	0.0361	0.5948	2.90	Algorithm converged.	1.05	7.95
	Female	372	50,5	2	0,5	396	52,9	10	2,5	0.21	Algorithm converged.	0.05	0.96	-1.988	Algorithm converged.	-3.70	-0.27	0.21	Algorithm converged.	0.05	0.97	0.0382		4.70	Algorithm converged.	1.04	21.30
Age	18-64	643	87,4	4	0,6	660	88,2	14	2,1	0.29	Algorithm converged.	0.09	0.88	-1.499	Algorithm converged.	-2.76	-0.24	0.29	Algorithm converged.	0.10	0.89	0.0300	0.7430	3.41	Algorithm converged.	1.13	10.30
	65-74	62	8,4	1	1,6	68	9,1	7	10,3	0.14	Algorithm converged.	0.02	1.20	-8.681	Algorithm converged.	-16.56	-0.81	0.16	Algorithm converged.	0.02	1.24	0.0642		6.38	Algorithm converged.	0.81	50.42
	>=75	31	4,2	2	6,5	20	2,7	3	15,0	0.39	Algorithm converged.	0.06	2.58	-8.548	Algorithm converged.	-26.43	9.33	0.43	Algorithm converged.	0.08	2.35	0.3685		2.33	Algorithm converged.	0.43	12.71
Baseline viral load categories	<=10^5 copies/mL	161	21,9	1	0,6	150	20,1	0	0,0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000	0.0652	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12,4	0	0,0	123	16,4	4	3,3	0.00	Algorithm converged.	NE	NE	-3.252	Algorithm converged.	-6.39	-0.12	NE *	Algorithm not converged.	NE	NE	0.1383		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16,2	0	0,0	125	16,7	5	4,0	0.00	Algorithm converged.	NE	NE	-4.000	Algorithm converged.	-7.44	-0.56	NE *	Algorithm not converged.	NE	NE	0.0603		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	49,3	6	1,7	346	46,3	15	4,3	0.37	Algorithm converged.	0.14	0.97	-2.682	Algorithm converged.	-5.20	-0.17	0.38	Algorithm converged.	0.15	0.97	0.0353		2.62	Algorithm converged.	1.03	6.68
	Unknown	2	0,3	0	0,0	4	0,5	0	0,0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94,8	7	1,0	711	95,1	22	3,1	0.32	Algorithm converged.	0.13	0.75	-2.091	Algorithm converged.	-3.56	-0.62	0.32	Algorithm converged.	0.14	0.75	0.0057	0.2905	3.09	Algorithm converged.	1.33	7.18
	MEX	38	5,2	0	0,0	37	4,9	2	5,4	0.00	Algorithm converged.	NE	NE	-5.405	Algorithm converged.	-12.69	1.88	NE *	Algorithm not converged.	NE	NE	0.2400		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67,9	3	0,6	519	69,4	18	3,5	0.17	Algorithm converged.	0.05	0.57	-2.866	Algorithm converged.	-4.58	-1.15	0.17	Algorithm converged.	0.05	0.58	0.0014	0.0046	5.78	Algorithm converged.	1.71	19.50
	Positive	177	24,0	1	0,6	164	21,9	6	3,7	0.15	Algorithm converged.	0.02	1.26	-3.094	Algorithm converged.	-6.17	-0.02	0.15	Algorithm converged.	0.02	1.27	0.0588		6.48	Algorithm converged.	0.79	53.22
	Other	59	8,0	3	5,1	65	8,7	0	0,0	NE *	Algorithm not converged.	NE	NE	5.085	Algorithm converged.	-0.52	10.69	NE *	Algorithm not converged.	NE	NE	0.1048		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-1-eff-resp-unstrat-tthos.xlsx, t12-1-eff-resp-unstrat-tthos.pdf

POPULATION: MFAS
 ENDPOINT: All-cause death at Day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	1	0,1	748	100,0	1	0,1	1.02	Algorithm converged.	0.06	16.32	0.002	Algorithm converged.	-0.37	0.38	1.02	Algorithm converged.	0.06	16.22	1.0000		0.98	Algorithm converged.	0.06	15.70

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-2-eff-resp-strat-dth29.xlsx, t12-2-eff-resp-strat-dth29.pdf

POPULATION: MFAS
 ENDPOINT: All-cause death at Day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroup analyses
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL				
All	n/a	736	100.0	1	0.1	748	100.0	1	0.1	1.02	Algorithm converged.	0.06	16.28	0.002	Algorithm converged.	-0.37	0.38	1.02	Algorithm converged.	0.06	16.22	1.0000		0.98	Algorithm converged.	0.06	15.70
Sex	Male	364	49.5	1	0.3	352	47.1	0	0.0	NR *	Algorithm not converged.	NE	NE	0.275	Algorithm converged.	-0.26	0.81	NR *	Algorithm not converged.	NE	NE	1.0000	0.1016	NR *	Algorithm not converged.	NE	NE
	Female	372	50.5	0	0.0	396	52.9	1	0.3	0.00	Algorithm converged.	NE	NE	-0.253	Algorithm converged.	-0.75	0.24	NR *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
Age	18-64	643	87.4	1	0.2	660	88.2	1	0.2	1.03	Algorithm converged.	0.06	16.45	0.004	Algorithm converged.	-0.42	0.43	1.03	Algorithm converged.	0.06	16.38	1.0000		0.97	Algorithm converged.	0.06	15.54
	65-74	62	8.4	0	0.0	68	9.1	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>=75	31	4.2	0	0.0	20	2.7	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NR *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NR *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	0	0.0	125	16.7	1	0.8	0.00	Algorithm converged.	NE	NE	-0.800	Algorithm converged.	-2.36	0.76	NR *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	263	35.8	0	0.0	246	33.0	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94.8	1	0.1	711	95.1	1	0.1	1.02	Algorithm converged.	0.06	16.32	0.003	Algorithm converged.	-0.39	0.40	1.02	Algorithm converged.	0.06	16.25	1.0000	1.0000	0.98	Algorithm converged.	0.06	15.66
	MEX	38	5.2	0	0.0	37	4.9	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	0	0.0	519	69.4	1	0.2	0.00	Algorithm converged.	NE	NE	-0.193	Algorithm converged.	-0.57	0.18	NR *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	Positive	177	24.0	1	0.6	164	21.9	0	0.0	NR *	Algorithm not converged.	NE	NE	0.565	Algorithm converged.	-0.54	1.67	NR *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	Other	59	8.0	0	0.0	65	8.7	0	0.0	NR *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NR *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-2-eff-resp-unstrat-dth29.xlsx, t12-2-eff-resp-unstrat-dth29.pdf

POPULATION: MFAS
 ENDPOINT: All-cause death at Day 169
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100.0	1	0.1	746	100.0	1	0.1	1.02	Algorithm converged.	0.06	16.32	0.002	Algorithm converged.	-0.37	0.36	1.02	Algorithm converged.	0.06	16.22	1.0000		0.98	Algorithm converged.	0.06	15.78

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-3-eff-resp-strat-dth169.xlsx, t12-3-eff-resp-strat-dth169.pdf

POPULATION: MFAS
 ENDPOINT: All-cause death at Day 169
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroups
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100.0	1	0.1	748	100.0	1	0.1	1.02	Algorithm converged.	0.06	16.28	0.002	Algorithm converged.	-0.37	0.38	1.02	Algorithm converged.	0.06	16.22	1.0000		0.98	Algorithm converged.	0.06	15.70
Sex	Male	364	49.5	1	0.3	352	47.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.275	Algorithm converged.	-0.26	0.81	NE *	Algorithm not converged.	NE	NE	1.0000	0.1016	NE *	Algorithm not converged.	NE	NE
	Female	372	50.5	0	0.0	396	52.9	1	0.3	0.00	Algorithm converged.	NE	NE	-0.253	Algorithm converged.	-0.75	0.24	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
Age	18-64	643	87.4	1	0.2	660	88.2	1	0.2	1.03	Algorithm converged.	0.06	16.45	0.004	Algorithm converged.	-0.42	0.43	1.03	Algorithm converged.	0.06	16.38	1.0000		0.97	Algorithm converged.	0.06	15.54
	65-74	62	8.4	0	0.0	68	9.1	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>=75	31	4.2	0	0.0	20	2.7	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	0	0.0	125	16.7	1	0.8	0.00	Algorithm converged.	NE	NE	-0.800	Algorithm converged.	-2.36	0.76	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	49.3	0	0.0	346	46.3	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94.8	1	0.1	711	95.1	1	0.1	1.02	Algorithm converged.	0.06	16.32	0.003	Algorithm converged.	-0.39	0.40	1.02	Algorithm converged.	0.06	16.25	1.0000	1.0000	0.98	Algorithm converged.	0.06	15.66
	MEX	38	5.2	0	0.0	37	4.9	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	0	0.0	519	69.4	1	0.2	0.00	Algorithm converged.	NE	NE	-0.193	Algorithm converged.	-0.57	0.18	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	Positive	177	24.0	1	0.6	164	21.9	0	0.0	NE *	Algorithm not converged.	NE	NE	0.565	Algorithm converged.	-0.54	1.67	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	Other	59	8.0	0	0.0	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-3-eff-resp-unstrat-dth169.xlsx, t12-3-eff-resp-unstrat-dth169.pdf

POPULATION: MFAS
 ENDPOINT: Hospitalization or all-cause death from day 4 through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab										
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	735	99,9	5	0,7	748	100,0	18	2,4	0,28	Algorithm converged.	0.10	0.75	-1.726	Algorithm converged.	-2.97	-0.48	0.28	Algorithm converged.	0.11	0.76	0.0101		3.54	Algorithm converged.	1.32	9.48

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-4-eff-resp-strat-tthos2.xlsx, t12-4-eff-resp-strat-tthos2.pdf

POPULATION: MFAS
 ENDPOINT: Hospitalization or all-cause death from day 4 through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroup analyses
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Interaction Test							
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL				
All	n/a	735	99.9	5	0.7	748	100.0	18	2.4	0.28	Algorithm converged.	0.10	0.75	-1.726	Algorithm converged.	-2.97	-0.48	0.28	Algorithm converged.	0.11	0.76	0.0101	3.54	Algorithm converged.	1.32	9.48	
Sex	Male	363	49.4	4	1.1	352	47.1	10	2.8	0.38	Algorithm converged.	0.12	1.23	-1.739	Algorithm converged.	-3.78	0.30	0.39	Algorithm converged.	0.12	1.23	0.1100	0.3448	2.58	Algorithm converged.	0.82	8.14
	Female	372	50.6	1	0.3	396	52.9	8	2.0	0.13	Algorithm converged.	0.02	1.05	-1.751	Algorithm converged.	-3.23	-0.27	0.13	Algorithm converged.	0.02	1.06	0.0388	7.52	Algorithm converged.	0.94	59.80	
Age	18-64	642	87.3	3	0.5	660	88.2	11	1.7	0.28	Algorithm converged.	0.08	1.00	-1.199	Algorithm converged.	-2.31	-0.09	0.28	Algorithm converged.	0.08	1.00	0.0564	0.9780	3.57	Algorithm converged.	1.00	12.73
	65-74	62	8.4	1	1.6	68	9.1	4	5.9	0.26	Algorithm converged.	0.03	2.41	-4.269	Algorithm converged.	-10.68	2.14	0.27	Algorithm converged.	0.03	2.39	0.3679	3.65	Algorithm converged.	0.42	31.75	
	>=75	31	4.2	1	3.2	20	2.7	3	15.0	0.19	Algorithm converged.	0.02	1.96	-11.774	Algorithm converged.	-28.61	5.07	0.22	Algorithm converged.	0.02	1.93	0.2867	4.65	Algorithm converged.	0.52	41.64	
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000	0.1638	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	2	1.6	0.00	Algorithm converged.	NE	NE	-1.626	Algorithm converged.	-3.86	0.61	NE *	Algorithm not converged.	NE	NE	0.5089	NE *	Algorithm not converged.	NE	NE	
	>10^6 copies/mL - <=10^7 copies/mL	118	16.1	0	0.0	125	16.7	3	2.4	0.00	Algorithm converged.	NE	NE	-2.400	Algorithm converged.	-5.08	0.28	NE *	Algorithm not converged.	NE	NE	0.2475	NE *	Algorithm not converged.	NE	NE	
	>10^7 copies/mL	363	49.4	4	1.1	346	46.3	13	3.8	0.29	Algorithm converged.	0.09	0.88	-2.655	Algorithm converged.	-4.93	-0.38	0.29	Algorithm converged.	0.10	0.89	0.0260	3.41	Algorithm converged.	1.12	10.36	
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE *	Algorithm not converged.	NE	NE	
Country	USA	697	94.8	5	0.7	711	95.1	18	2.5	0.28	Algorithm converged.	0.10	0.75	-1.814	Algorithm converged.	-3.13	-0.50	0.28	Algorithm converged.	0.11	0.76	0.0101	1.0000	3.53	Algorithm converged.	1.32	9.45
	MEX	38	5.2	0	0.0	37	4.9	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE *	Algorithm not converged.	NE	NE	
Baseline serostatus	Negative	500	68.0	2	0.4	519	69.4	15	2.9	0.13	Algorithm converged.	0.03	0.59	-2.490	Algorithm converged.	-4.03	-0.95	0.14	Algorithm converged.	0.03	0.60	0.0022	0.0225	7.23	Algorithm converged.	1.66	31.43
	Positive	177	24.1	1	0.6	164	21.9	3	1.8	0.30	Algorithm converged.	0.03	2.96	-1.264	Algorithm converged.	-3.59	1.07	0.31	Algorithm converged.	0.03	2.94	0.3547	3.24	Algorithm converged.	0.34	30.82	
	Other	58	7.9	2	3.4	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	3.448	Algorithm converged.	-1.25	8.14	NE *	Algorithm not converged.	NE	NE	0.2203	NE *	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-4-eff-resp-unstrat-tthos2.xlsx, t12-4-eff-resp-unstrat-tthos2.pdf

POPULATION: MFAS
 ENDPOINT: Hospitalization or ER visit or all-cause death through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	9	1,2	748	100,0	34	4,5	0,26	Algorithm converged.	0,12	0,55	-3,323	Algorithm converged.	-5,01	-1,63	0,27	Algorithm converged.	0,13	0,56	0,0001		3,72	Algorithm converged.	1,80	7,70

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-5-eff-resp-strat-tthcvd.xlsx, t12-5-eff-resp-strat-tthcvd.pdf

POPULATION: MFAS
 ENDPOINT: Hospitalization or ER visit or all-cause death through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroup analyses
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Interaction Test							
n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL						
All	n/a	736	100.0	9	1.2	748	100.0	34	4.5	0.26	Algorithm converged.	0.12	0.55	-3.323	Algorithm converged.	-5.01	-1.63	0.27	Algorithm converged.	0.13	0.56	0.0001		3.72	Algorithm converged.	1.80	7.70
Sex	Male	364	49.5	7	1.9	352	47.1	19	5.4	0.34	Algorithm converged.	0.14	0.83	-3.475	Algorithm converged.	-6.22	-0.72	0.36	Algorithm converged.	0.15	0.84	0.0130	0.2629	2.81	Algorithm converged.	1.19	6.59
	Female	372	50.5	2	0.5	396	52.9	15	3.8	0.14	Algorithm converged.	0.03	0.60	-3.250	Algorithm converged.	-5.27	-1.23	0.14	Algorithm converged.	0.03	0.62	0.0023		7.05	Algorithm converged.	1.62	30.60
Age	18-64	643	87.4	5	0.8	660	88.2	21	3.2	0.24	Algorithm converged.	0.09	0.64	-2.404	Algorithm converged.	-3.91	-0.90	0.24	Algorithm converged.	0.09	0.64	0.0023	0.9560	4.09	Algorithm converged.	1.55	10.79
	65-74	62	8.4	2	3.2	68	9.1	9	13.2	0.22	Algorithm converged.	0.05	1.05	-10.009	Algorithm converged.	-19.19	-0.83	0.24	Algorithm converged.	0.05	1.08	0.0574		4.10	Algorithm converged.	0.92	18.26
	>=75	31	4.2	2	6.5	20	2.7	4	20.0	0.28	Algorithm converged.	0.05	1.68	-13.548	Algorithm converged.	-33.10	6.00	0.32	Algorithm converged.	0.07	1.60	0.1948		3.10	Algorithm converged.	0.62	15.38
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	3	2.0	0.31	Algorithm converged.	0.03	2.98	-1.379	Algorithm converged.	-3.93	1.17	0.31	Algorithm converged.	0.03	2.95	0.3557	0.4661	3.22	Algorithm converged.	0.34	30.62
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	5	4.1	0.00	Algorithm converged.	NE	NE	-4.065	Algorithm converged.	-7.55	-0.58	NE *	Algorithm not converged.	NE	NE	0.0736		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	1	0.8	125	16.7	7	5.6	0.14	Algorithm converged.	0.02	1.18	-4.760	Algorithm converged.	-9.11	-0.41	0.15	Algorithm converged.	0.02	1.20	0.0665		6.66	Algorithm converged.	0.83	53.35
	>10^7 copies/mL	363	49.3	7	1.9	346	46.3	19	5.5	0.34	Algorithm converged.	0.14	0.82	-3.563	Algorithm converged.	-6.35	-0.78	0.35	Algorithm converged.	0.15	0.82	0.0117		2.85	Algorithm converged.	1.21	6.69
Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE	
Country	USA	698	94.8	9	1.3	711	95.1	32	4.5	0.28	Algorithm converged.	0.13	0.59	-3.211	Algorithm converged.	-4.95	-1.47	0.29	Algorithm converged.	0.14	0.60	0.0003	0.3139	3.49	Algorithm converged.	1.68	7.26
	MEX	38	5.2	0	0.0	37	4.9	2	5.4	0.00	Algorithm converged.	NE	NE	-5.405	Algorithm converged.	-12.69	1.88	NE *	Algorithm not converged.	NE	NE	0.2400		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	4	0.8	519	69.4	26	5.0	0.15	Algorithm converged.	0.05	0.44	-4.210	Algorithm converged.	-6.24	-2.18	0.16	Algorithm converged.	0.06	0.45	<0.0001	0.0039	6.26	Algorithm converged.	2.20	17.81
	Positive	177	24.0	2	1.1	164	21.9	8	4.9	0.22	Algorithm converged.	0.05	1.07	-3.748	Algorithm converged.	-7.39	-0.10	0.23	Algorithm converged.	0.05	1.07	0.0537		4.32	Algorithm converged.	0.93	20.03
	Other	59	8.0	3	5.1	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	5.085	Algorithm converged.	-0.52	10.69	NE *	Algorithm not converged.	NE	NE	0.1048		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-5-eff-resp-unstrat-tthcvd.xlsx, t12-5-eff-resp-unstrat-tthcvd.pdf

POPULATION: MFAS
 ENDPOINT: Hospitalization through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	7	1,0	748	100,0	24	3,2	0.29	Algorithm converged.	0.12	0.68	-2.257	Algorithm converged.	-3.70	-0.81	0.30	Algorithm converged.	0.13	0.68	0.0024		3.37	Algorithm converged.	1.46	7.78

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-6-eff-resp-unstrat-hosp.xlsx, t12-6-eff-resp-unstrat-hosp.pdf

POPULATION: MFAS
 ENDPOINT: Hospitalization through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroup analyses
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Experimental vs. Control										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CI	95% Upper CI				
All	n/a	736	100.0	7	1.0	748	100.0	24	3.2	0.29	Algorithm converged.	0.12	0.68	-2.257	Algorithm converged.	-3.70	-0.81	0.30	Algorithm converged.	0.13	0.68	0.0024		3.37	Algorithm converged.	1.46	7.78
Sex	Male	364	49.5	5	1.4	352	47.1	14	4.0	0.34	Algorithm converged.	0.12	0.94	-2.604	Algorithm converged.	-4.97	-0.24	0.35	Algorithm converged.	0.13	0.95	0.0361	0.5948	2.90	Algorithm converged.	1.05	7.95
	Female	372	50.5	2	0.5	396	52.9	10	2.5	0.21	Algorithm converged.	0.05	0.96	-1.988	Algorithm converged.	-3.70	-0.27	0.21	Algorithm converged.	0.05	0.97	0.0382		4.70	Algorithm converged.	1.04	21.30
Age	18-64	643	87.4	4	0.6	660	88.2	14	2.1	0.29	Algorithm converged.	0.09	0.88	-1.499	Algorithm converged.	-2.76	-0.24	0.29	Algorithm converged.	0.10	0.89	0.0300	0.7430	3.41	Algorithm converged.	1.13	10.30
	65-74	62	8.4	1	1.6	68	9.1	7	10.3	0.14	Algorithm converged.	0.02	1.20	-8.681	Algorithm converged.	-16.56	-0.81	0.16	Algorithm converged.	0.02	1.24	0.0642		6.38	Algorithm converged.	0.81	50.42
	>=75	31	4.2	2	6.5	20	2.7	3	15.0	0.39	Algorithm converged.	0.06	2.58	-8.548	Algorithm converged.	-26.43	9.33	0.43	Algorithm converged.	0.08	2.35	0.3685		2.33	Algorithm converged.	0.43	12.71
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000	0.0652	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	4	3.3	0.00	Algorithm converged.	NE	NE	-3.252	Algorithm converged.	-6.39	-0.12	NE *	Algorithm not converged.	NE	NE	0.1383		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	0	0.0	125	16.7	5	4.0	0.00	Algorithm converged.	NE	NE	-4.000	Algorithm converged.	-7.44	-0.56	NE *	Algorithm not converged.	NE	NE	0.0603		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	49.3	6	1.7	346	46.3	15	4.3	0.37	Algorithm converged.	0.14	0.97	-2.682	Algorithm converged.	-5.20	-0.17	0.38	Algorithm converged.	0.15	0.97	0.0353		2.62	Algorithm converged.	1.03	6.68
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94.8	7	1.0	711	95.1	22	3.1	0.32	Algorithm converged.	0.13	0.75	-2.091	Algorithm converged.	-3.56	-0.62	0.32	Algorithm converged.	0.14	0.75	0.0057	0.2905	3.09	Algorithm converged.	1.33	7.18
	MEX	38	5.2	0	0.0	37	4.9	2	5.4	0.00	Algorithm converged.	NE	NE	-5.405	Algorithm converged.	-12.69	1.88	NE *	Algorithm not converged.	NE	NE	0.2400		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	3	0.6	519	69.4	18	3.5	0.17	Algorithm converged.	0.05	0.57	-2.868	Algorithm converged.	-4.58	-1.15	0.17	Algorithm converged.	0.05	0.58	0.0014	0.0046	5.78	Algorithm converged.	1.71	19.50
	Positive	177	24.0	1	0.6	164	21.9	6	3.7	0.15	Algorithm converged.	0.02	1.26	-3.094	Algorithm converged.	-6.17	-0.02	0.15	Algorithm converged.	0.02	1.27	0.0588		6.48	Algorithm converged.	0.79	53.22
	Other	59	8.0	3	5.1	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	5.085	Algorithm converged.	-0.52	10.69	NE *	Algorithm not converged.	NE	NE	0.1048		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-6-eff-resp-unstrat-hosp.xlsx, t12-6-eff-resp-unstrat-hosp.pdf

POPULATION: MFAS
 ENDPPOINT: ER visit through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab										
Name	Level	Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	3	0,4	748	100,0	12	1,6	0.25	Algorithm converged.	0.07	0.89	-1.197	Algorithm converged.	-2.21	-0.19	0.25	Algorithm converged.	0.07	0.90	0.0343		3.94	Algorithm converged.	1.12	13.89

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-7-eff-resp-unstrat-er.xlsx, t12-7-eff-resp-unstrat-er.pdf

POPULATION: MFAS
 ENDPOINT: ER visit through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroup analyses
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Interaction Test p-value (likelihood ratio)								
n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	95% Lower CL	95% Upper CL	p-value	Relative Risk	95% Lower CL		95% Upper CL							
All	n/a	736	100.0	3	0.4	748	100.0	12	1.6	0.25	Algorithm converged.	0.07	0.89	-1.197	Algorithm converged.	-2.21	-0.19	0.25	Algorithm converged.	0.07	0.90	0.0343		3.94	Algorithm converged.	1.12	13.89	
Sex	Male	364	49.5	3	0.8	352	47.1	7	2.0	0.41	Algorithm converged.	0.11	1.60	-1.164	Algorithm converged.	-2.89	0.56	0.41	Algorithm converged.	0.11	1.59	0.2163	0.1057	2.41	Algorithm converged.	0.63	9.26	
	Female	372	50.5	0	0.0	396	52.9	5	1.3	0.00	Algorithm converged.	NE	NE	-1.263	Algorithm converged.	-2.36	-0.16	NE	Algorithm not converged.	NE	NE	0.0623	NE	NE	Algorithm not converged.	NE	NE	
Age	18-64	643	87.4	2	0.3	660	88.2	8	1.2	0.25	Algorithm converged.	0.05	1.20	-0.901	Algorithm converged.	-1.84	0.04	0.26	Algorithm converged.	0.05	1.20	0.1083	0.6818	3.90	Algorithm converged.	0.83	18.28	
	65-74	62	8.4	1	1.6	68	9.1	3	4.4	0.36	Algorithm converged.	0.04	3.51	-2.799	Algorithm converged.	-8.60	3.00	0.37	Algorithm converged.	0.04	3.42	0.6208		2.74	Algorithm converged.	0.29	25.61	
	>=75	31	4.2	0	0.0	20	2.7	1	5.0	0.00	Algorithm converged.	NE	NE	-5.000	Algorithm converged.	-14.55	4.55	NE	Algorithm not converged.	NE	NE	0.3922	NE	NE	Algorithm not converged.	NE	NE	
Baseline viral load categories	<=10 ⁵ copies/mL	161	21.9	0	0.0	150	20.1	3	2.0	0.00	Algorithm converged.	NE	NE	-2.000	Algorithm converged.	-4.24	0.24	NE	Algorithm not converged.	NE	NE	0.1110	0.5339	NE	NE	Algorithm not converged.	NE	NE
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	91	12.4	0	0.0	123	16.4	1	0.8	0.00	Algorithm converged.	NE	NE	-0.813	Algorithm converged.	-2.40	0.77	NE	Algorithm not converged.	NE	NE	1.0000		NE	NE	Algorithm not converged.	NE	NE
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	16.2	1	0.8	125	16.7	2	1.6	0.52	Algorithm converged.	0.05	5.82	-0.760	Algorithm converged.	-3.50	1.98	0.53	Algorithm converged.	0.05	5.72	1.0000		1.90	Algorithm converged.	0.17	20.72	
	>10 ⁷ copies/mL	363	49.3	2	0.6	346	46.3	6	1.7	0.31	Algorithm converged.	0.06	1.57	-1.183	Algorithm converged.	-2.76	0.39	0.32	Algorithm converged.	0.06	1.56	0.1679		3.15	Algorithm converged.	0.64	15.49	
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	NE	Algorithm not converged.	NE	NE
Country	USA	698	94.8	3	0.4	711	95.1	12	1.7	0.25	Algorithm converged.	0.07	0.89	-1.258	Algorithm converged.	-2.32	-0.19	0.25	Algorithm converged.	0.07	0.90	0.0343	1.0000	3.93	Algorithm converged.	1.11	13.86	
	MEX	38	5.2	0	0.0	37	4.9	0	0.0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	NE	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	2	0.4	519	69.4	9	1.7	0.23	Algorithm converged.	0.05	1.06	-1.334	Algorithm converged.	-2.59	-0.08	0.23	Algorithm converged.	0.05	1.06	0.0645	0.9786	4.34	Algorithm converged.	0.94	19.97	
	Positive	177	24.0	1	0.6	164	21.9	3	1.8	0.30	Algorithm converged.	0.03	2.96	-1.264	Algorithm converged.	-3.59	1.07	0.31	Algorithm converged.	0.03	2.94	0.3547		3.24	Algorithm converged.	0.34	30.82	
	Other	59	8.0	0	0.0	65	8.7	0	0.0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-7-eff-resp-unstrat-er.xlsx, t12-7-eff-resp-unstrat-er.pdf

POPULATION: MFAS
 ENDPOINT: Mechanical ventilation through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	1	0,1	748	100,0	2	0,3	0.51	Algorithm converged.	0.05	5.62	-0.132	Algorithm converged.	-0.59	0.32	0.51	Algorithm converged.	0.05	5.59	1.0000		1.97	Algorithm converged.	0.18	21.66

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-8-eff-resp-unstrat-mecvent.xlsx, t12-8-eff-resp-unstrat-mecvent.pdf

POPULATION: MFAS
 ENDPOINT: Mechanical ventilation through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroups
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Experimental vs. Control										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference						Relative Risk		Relative Risk		Interaction Test p-value (likelihood ratio)	Relative Risk	Relative Risk			
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL			p-value	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100.0	1	0.1	748	100.0	2	0.3	0.51	Algorithm converged.	0.05	5.61	-0.132	Algorithm converged.	-0.59	0.32	0.51	Algorithm converged.	0.05	5.59	1.0000		1.97	Algorithm converged.	0.18	21.66
Sex	Male	364	49.5	1	0.3	352	47.1	1	0.3	0.97	Algorithm converged.	0.06	15.52	-0.009	Algorithm converged.	-0.78	0.76	0.97	Algorithm converged.	0.06	15.40	1.0000	0.3210	1.03	Algorithm converged.	0.06	16.47
	Female	372	50.5	0	0.0	396	52.9	1	0.3	0.00	Algorithm converged.	NE	NE	-0.253	Algorithm converged.	-0.75	0.24	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
Age	18-64	643	87.4	1	0.2	660	88.2	1	0.2	1.03	Algorithm converged.	0.06	16.45	0.004	Algorithm converged.	-0.42	0.43	1.03	Algorithm converged.	0.06	16.38	1.0000		0.97	Algorithm converged.	0.06	15.54
	65-74	62	8.4	0	0.0	68	9.1	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>=75	31	4.2	0	0.0	20	2.7	1	5.0	0.00	Algorithm converged.	NE	NE	-5.000	Algorithm converged.	-14.55	4.55	NE *	Algorithm not converged.	NE	NE	0.3922		NE *	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	0	0.0	125	16.7	1	0.8	0.00	Algorithm converged.	NE	NE	-0.800	Algorithm converged.	-2.36	0.76	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	49.3	0	0.0	346	46.3	1	0.3	0.00	Algorithm converged.	NE	NE	-0.289	Algorithm converged.	-0.85	0.28	NE *	Algorithm not converged.	NE	NE	0.4880		NE *	Algorithm not converged.	NE	NE
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94.8	1	0.1	711	95.1	2	0.3	0.51	Algorithm converged.	0.05	5.62	-0.138	Algorithm converged.	-0.62	0.34	0.51	Algorithm converged.	0.05	5.60	1.0000	1.0000	1.96	Algorithm converged.	0.18	21.60
	MEX	38	5.2	0	0.0	37	4.9	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	0	0.0	519	69.4	1	0.2	0.00	Algorithm converged.	NE	NE	-0.193	Algorithm converged.	-0.57	0.18	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	Positive	177	24.0	1	0.6	164	21.9	1	0.6	0.93	Algorithm converged.	0.06	14.93	-0.045	Algorithm converged.	-1.67	1.58	0.93	Algorithm converged.	0.06	14.69	1.0000		1.08	Algorithm converged.	0.07	17.11
	Other	59	8.0	0	0.0	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 18Feb2021

Program: L-eff-resp.sas, binary1-excel.sas
 Output: t12-8-eff-resp-unstrat-mecvent.xlsx, t12-8-eff-resp-unstrat-mecvent.pdf

POPULATION: MFAS
 ENDPOINT: Supplemental oxygen through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
Name	Level	Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	4	0,5	748	100,0	16	2,1	0.25	Algorithm converged.	0.08	0.75	-1.596	Algorithm converged.	-2.76	-0.43	0.25	Algorithm converged.	0.09	0.76	0.0113		3.94	Algorithm converged.	1.32	11.72

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-9-eff-resp-unstrat-oxysup.xlsx, t12-9-eff-resp-unstrat-oxysup.pdf

POPULATION: MFAS
 ENDPOINT: Supplemental oxygen through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroups
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk				
n	%	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	736	100.0	4	0.5	748	100.0	16	2.1	0.25	Algorithm converged.	0.08	0.75	-1.596	Algorithm converged.	-2.76	-0.43	0.25	Algorithm converged.	0.09	0.76	0.0113		3.94	Algorithm converged.	1.32	11.72
Sex	Male	364	49.5	2	0.5	352	47.1	9	2.6	0.21	Algorithm converged.	0.05	0.98	-2.007	Algorithm converged.	-3.82	-0.19	0.21	Algorithm converged.	0.05	0.99	0.0344	0.7556	4.65	Algorithm converged.	1.01	21.39
	Female	372	50.5	2	0.5	396	52.9	7	1.8	0.30	Algorithm converged.	0.06	1.46	-1.230	Algorithm converged.	-2.73	0.27	0.30	Algorithm converged.	0.06	1.45	0.1790		3.29	Algorithm converged.	0.69	15.73
Age	18-64	643	87.4	2	0.3	660	88.2	11	1.7	0.18	Algorithm converged.	0.04	0.83	-1.356	Algorithm converged.	-2.42	-0.29	0.19	Algorithm converged.	0.04	0.84	0.0220	***	5.36	Algorithm converged.	1.19	24.08
	65-74	62	8.4	0	0.0	68	9.1	3	4.4	0.00	Algorithm converged.	NE	NE	-4.412	Algorithm converged.	-9.29	0.47	NE *	Algorithm not converged.	NE	NE	0.2458		NE *	Algorithm not converged.	NE	NE
	>=75	31	4.2	2	6.5	20	2.7	2	10.0	0.62	Algorithm converged.	0.08	4.80	-3.548	Algorithm converged.	-19.29	12.19	0.65	Algorithm converged.	0.10	4.22	0.6403		1.55	Algorithm converged.	0.24	10.13
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000	0.1657	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	2	1.6	0.00	Algorithm converged.	NE	NE	-1.626	Algorithm converged.	-3.86	0.61	NE *	Algorithm not converged.	NE	NE	0.5089		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	0	0.0	125	16.7	3	2.4	0.00	Algorithm converged.	NE	NE	-2.400	Algorithm converged.	-5.08	0.28	NE *	Algorithm not converged.	NE	NE	0.2474		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	49.3	3	0.8	346	46.3	11	3.2	0.25	Algorithm converged.	0.07	0.92	-2.353	Algorithm converged.	-4.42	-0.28	0.26	Algorithm converged.	0.07	0.92	0.0300		3.85	Algorithm converged.	1.08	13.67
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94.8	4	0.6	711	95.1	14	2.0	0.29	Algorithm converged.	0.09	0.88	-1.396	Algorithm converged.	-2.56	-0.23	0.29	Algorithm converged.	0.10	0.88	0.0300	0.3190	3.44	Algorithm converged.	1.14	10.39
	MEX	38	5.2	0	0.0	37	4.9	2	5.4	0.00	Algorithm converged.	NE	NE	-5.405	Algorithm converged.	-12.69	1.88	NE *	Algorithm not converged.	NE	NE	0.2400		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	1	0.2	519	69.4	12	2.3	0.08	Algorithm converged.	0.01	0.65	-2.112	Algorithm converged.	-3.46	-0.76	0.09	Algorithm converged.	0.01	0.66	0.0033	0.0161	11.56	Algorithm converged.	1.51	88.58
	Positive	177	24.0	1	0.6	164	21.9	4	2.4	0.23	Algorithm converged.	0.03	2.05	-1.874	Algorithm converged.	-4.48	0.73	0.23	Algorithm converged.	0.03	2.05	0.1994		4.32	Algorithm converged.	0.49	38.23
	Other	59	8.0	2	3.4	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	3.390	Algorithm converged.	-1.23	8.01	NE *	Algorithm not converged.	NE	NE	0.2244		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 *** indicate GCMOD returns inevitable errors: "The mean parameter is either invalid or at a limit of its range for some observations." The specified model constrained by contrast treatment*subgroup does not converge.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-9-eff-resp-unstrat-oxysup.xlsx, t12-9-eff-resp-unstrat-oxysup.pdf

POPULATION: MFAS
 ENDPOINT: Admission to ICU through day 29
 MODEL: Stratified analysis for overall; stratification factor = country
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	736	100,0	3	0,4	748	100,0	7	0,9	0.43	Algorithm converged.	0.11	1.69	-0.528	Algorithm converged.	-1.36	0.30	0.44	Algorithm converged.	0.11	1.68	0.3422		2.30	Algorithm converged.	0.60	8.84

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-10-eff-resp-unstrat-icu.xlsx, t12-10-eff-resp-unstrat-icu.pdf

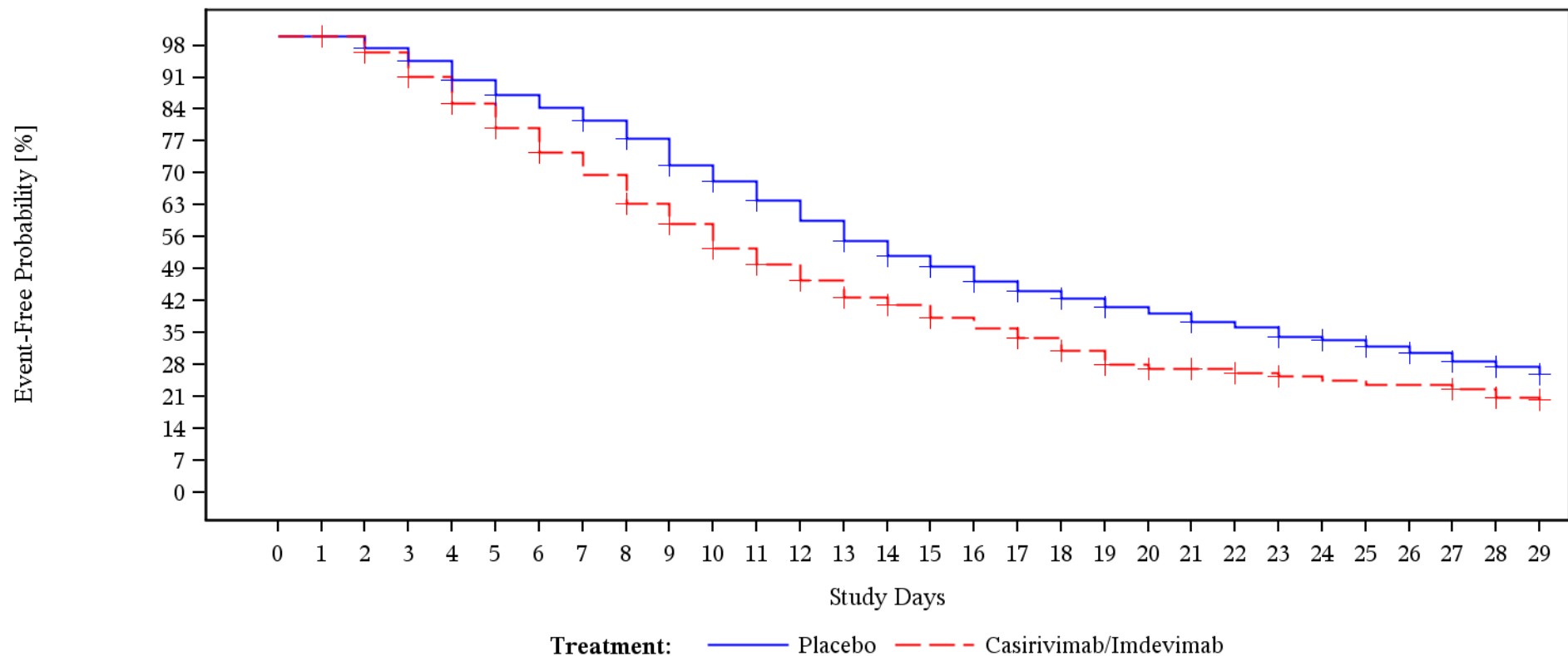
POPULATION: MFAS
 ENDPOINT: Admission to ICU through day 29
 MODEL: Unstratified analysis for overall; Unstratified analysis for subgroups
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio	Absolute Risk Difference		Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Absolute Risk	95% Lower CI	95% Upper CI	Relative Risk	95% Lower CI	95% Upper CI	p-value		Relative Risk	95% Lower CI	95% Upper CI				
All	n/a	736	100.0	3	0.4	748	100.0	7	0.9	0.43	Algorithm converged.	0.11	1.68	-0.528	Algorithm converged.	-1.36	0.30	0.44	Algorithm converged.	0.11	1.68	0.3422		2.30	Algorithm converged.	0.60	8.84
Sex	Male	364	49.5	2	0.5	352	47.1	4	1.1	0.48	Algorithm converged.	0.09	2.64	-0.587	Algorithm converged.	-1.93	0.76	0.48	Algorithm converged.	0.09	2.62	0.4439	0.8285	2.07	Algorithm converged.	0.38	11.22
	Female	372	50.5	1	0.3	396	52.9	3	0.8	0.35	Algorithm converged.	0.04	3.41	-0.489	Algorithm converged.	-1.49	0.51	0.35	Algorithm converged.	0.04	3.40	0.6248		2.82	Algorithm converged.	0.29	26.97
Age	18-64	643	87.4	3	0.5	660	88.2	2	0.3	1.54	Algorithm converged.	0.26	9.26	0.164	Algorithm converged.	-0.51	0.84	1.54	Algorithm converged.	0.26	9.18	0.6830	0.0476	0.65	Algorithm converged.	0.11	3.87
	65-74	62	8.4	0	0.0	68	9.1	3	4.4	0.00	Algorithm converged.	NE	NE	-4.412	Algorithm converged.	-9.29	0.47	NE *	Algorithm not converged.	NE	NE	0.2458		NE *	Algorithm not converged.	NE	NE
	>=75	31	4.2	0	0.0	20	2.7	2	10.0	0.00	Algorithm converged.	NE	NE	-10.000	Algorithm converged.	-23.15	3.15	NE *	Algorithm not converged.	NE	NE	0.1490		NE *	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	161	21.9	1	0.6	150	20.1	0	0.0	NE *	Algorithm not converged.	NE	NE	0.621	Algorithm converged.	-0.59	1.83	NE *	Algorithm not converged.	NE	NE	1.0000	0.2486	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	91	12.4	0	0.0	123	16.4	2	1.6	0.00	Algorithm converged.	NE	NE	-1.626	Algorithm converged.	-3.86	0.61	NE *	Algorithm not converged.	NE	NE	0.5089		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	16.2	0	0.0	125	16.7	1	0.8	0.00	Algorithm converged.	NE	NE	-0.800	Algorithm converged.	-2.36	0.76	NE *	Algorithm not converged.	NE	NE	1.0000		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	49.3	2	0.6	346	46.3	4	1.2	0.47	Algorithm converged.	0.09	2.60	-0.605	Algorithm converged.	-1.96	0.75	0.48	Algorithm converged.	0.09	2.59	0.4408		2.10	Algorithm converged.	0.39	11.38
	Unknown	2	0.3	0	0.0	4	0.5	0	0.0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	698	94.8	3	0.4	711	95.1	7	1.0	0.43	Algorithm converged.	0.11	1.69	-0.555	Algorithm converged.	-1.43	0.32	0.44	Algorithm converged.	0.11	1.68	0.3422	1.0000	2.29	Algorithm converged.	0.59	8.82
	MEX	38	5.2	0	0.0	37	4.9	0	0.0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	500	67.9	1	0.2	519	69.4	2	0.4	0.52	Algorithm converged.	0.05	5.73	-0.185	Algorithm converged.	-0.85	0.48	0.52	Algorithm converged.	0.05	5.71	1.0000	0.1929	1.93	Algorithm converged.	0.18	21.18
	Positive	177	24.0	1	0.6	164	21.9	5	3.0	0.18	Algorithm converged.	0.02	1.56	-2.484	Algorithm converged.	-5.34	0.37	0.19	Algorithm converged.	0.02	1.57	0.1093		5.40	Algorithm converged.	0.64	45.71
	Other	59	8.0	1	1.7	65	8.7	0	0.0	NE *	Algorithm not converged.	NE	NE	1.695	Algorithm converged.	-1.60	4.99	NE *	Algorithm not converged.	NE	NE	0.4758		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-resp.sas, binary1-excel.sas
 Output: t12-10-eff-resp-unstrat-icu.xlsx, t12-10-eff-resp-unstrat-icu.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	533	513	496	471	450	435	419	396	363	345	322	300	277	258	246	227	215	206	196	189	178	173	162	157	150	138	123	86
Casirivimab/Imdevimab	736	736	534	514	485	452	423	393	367	332	307	278	259	239	219	208	193	182	170	154	138	132	130	124	118	114	110	110	100	58

Patients Censored

Placebo	0	215	221	224	226	231	231	233	235	238	239	240	240	241	243	244	246	248	249	250	250	252	252	253	254	255	260	267	299	380
Casirivimab/Imdevimab	0	202	203	204	205	206	208	208	210	211	212	213	215	216	218	219	219	220	222	223	224	226	228	230	230	230	230	235	269	326

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-tsres.pdf

POPULATION: mFAS
 ENDPOINT: Time to COVID-19 symptoms resolution
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	410	55,7	326	44,3	6,00	6,00	7,00	11,00	10,00	13,00	746	100,0	368	49,2	380	50,8	9,00	8,00	10,00	15,00	14,00	17,00	0,0001	1,32	1,14	1,52	Convergence criterion (GCONV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-1-eff-tte-tsres

POPULATION: mFAS
 ENDPOINT: Time to COVID-19 symptoms resolution
 MODEL: --
 STUDY: R10933-10987-COV-2067
 Template Compliance/Mean

		Casirivimab/Imdevimab (N=736)						Placebo (N=748)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
Visit													
All													
Baseline	All	736	100,0	673	91,4			748	100,0	680	90,9		
Day 2	All	736	100,0	622	84,5			748	100,0	626	83,7		
Day 3	All	736	100,0	632	85,9			748	100,0	617	82,5		
Day 4	All	735	99,9	619	84,2			748	100,0	603	80,6		
Day 5	All	734	99,7	603	82,2			748	100,0	598	79,9		
Day 6	All	734	99,7	603	82,2			748	100,0	592	79,1		
Day 7	All	733	99,6	546	74,5			748	100,0	531	71,0		
Day 8	All	733	99,6	579	79,0			747	99,9	571	76,4		
Day 9	All	733	99,6	578	78,9			747	99,9	556	74,4		
Day 10	All	733	99,6	568	77,5			746	99,7	551	73,9		
Day 11	All	733	99,6	564	76,9			744	99,5	551	74,1		
Day 12	All	733	99,6	557	76,0			744	99,5	545	73,3		
Day 13	All	733	99,6	558	76,1			744	99,5	550	73,9		
Day 14	All	733	99,6	554	75,6			743	99,3	538	72,4		
Day 15	All	733	99,6	428	58,4			743	99,3	429	57,7		
Day 16	All	732	99,5	546	74,6			743	99,3	530	71,3		
Day 17	All	732	99,5	524	71,6			743	99,3	524	70,5		
Day 18	All	732	99,5	538	73,5			743	99,3	522	70,3		
Day 19	All	731	99,3	554	75,8			743	99,3	516	69,4		
Day 20	All	731	99,3	542	74,1			743	99,3	539	72,5		
Day 21	All	730	99,2	523	71,6			743	99,3	512	68,9		
Day 22	All	730	99,2	547	74,9			741	99,1	511	69,0		
Day 23	All	730	99,2	538	73,7			741	99,1	512	69,1		
Day 24	All	730	99,2	516	70,7			741	99,1	495	66,8		
Day 25	All	730	99,2	518	71,0			741	99,1	512	69,1		
Day 26	All	730	99,2	518	71,0			741	99,1	497	67,1		
Day 27	All	730	99,2	509	69,7			740	98,9	503	68,0		
Day 28	All	730	99,2	497	68,1			739	98,8	480	65,0		
Day 29	All	730	99,2	327	44,8			738	98,7	331	44,9		
Day 30	All	730	99,2	9	1,2			738	98,7	10	1,4		
Day 31	All	730	99,2	1	0,1			738	98,7	2	0,3		
Day 32	All	729	99,0	0	0,0			738	98,7	3	0,4		
Day 33	All	729	99,0	0	0,0			738	98,7	2	0,3		
Day 34	All	729	99,0	0	0,0			738	98,7	2	0,3		

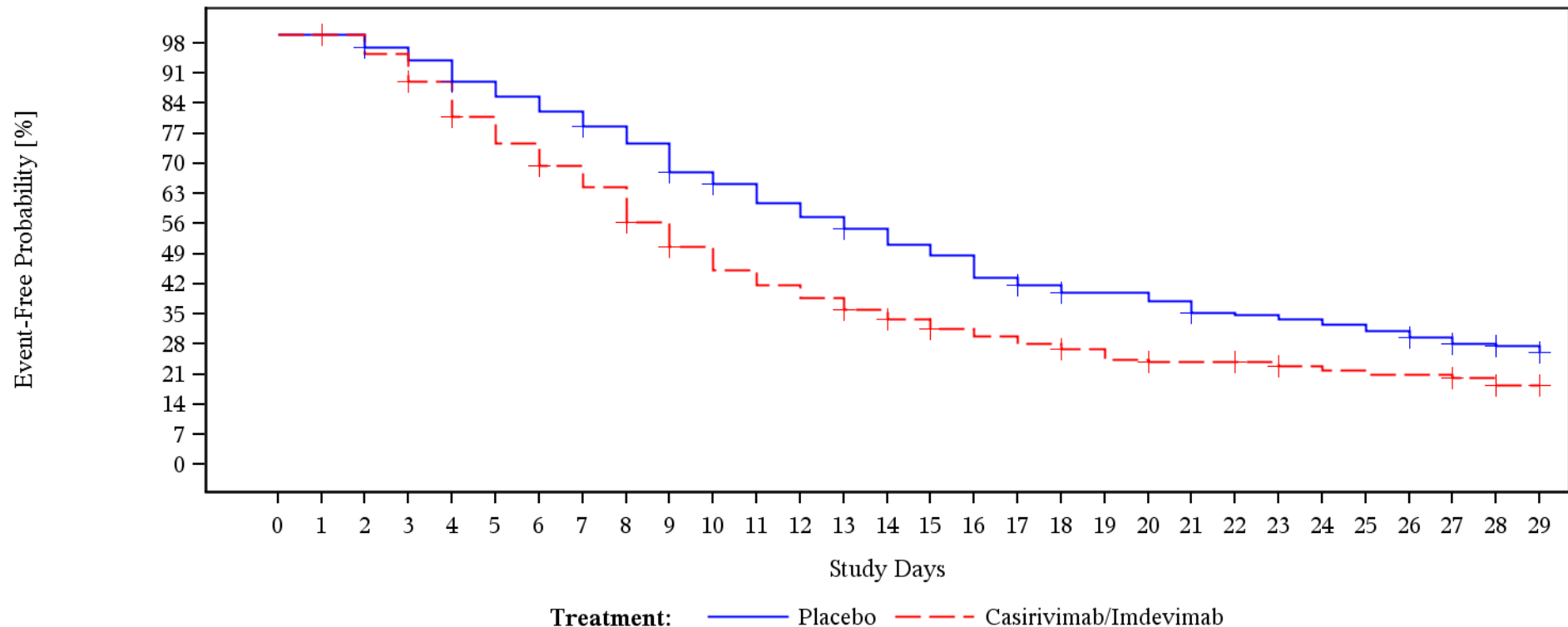
¹ in study: number of subjects in study at respective visit; % based on baseline
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values

Clinical cut-off: 18Feb2021

Program: t-eff-mean.sas

Output: t14-5-eff-mean-overall-sec19.xlsx, t14-5-eff-mean-overall-sec19.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

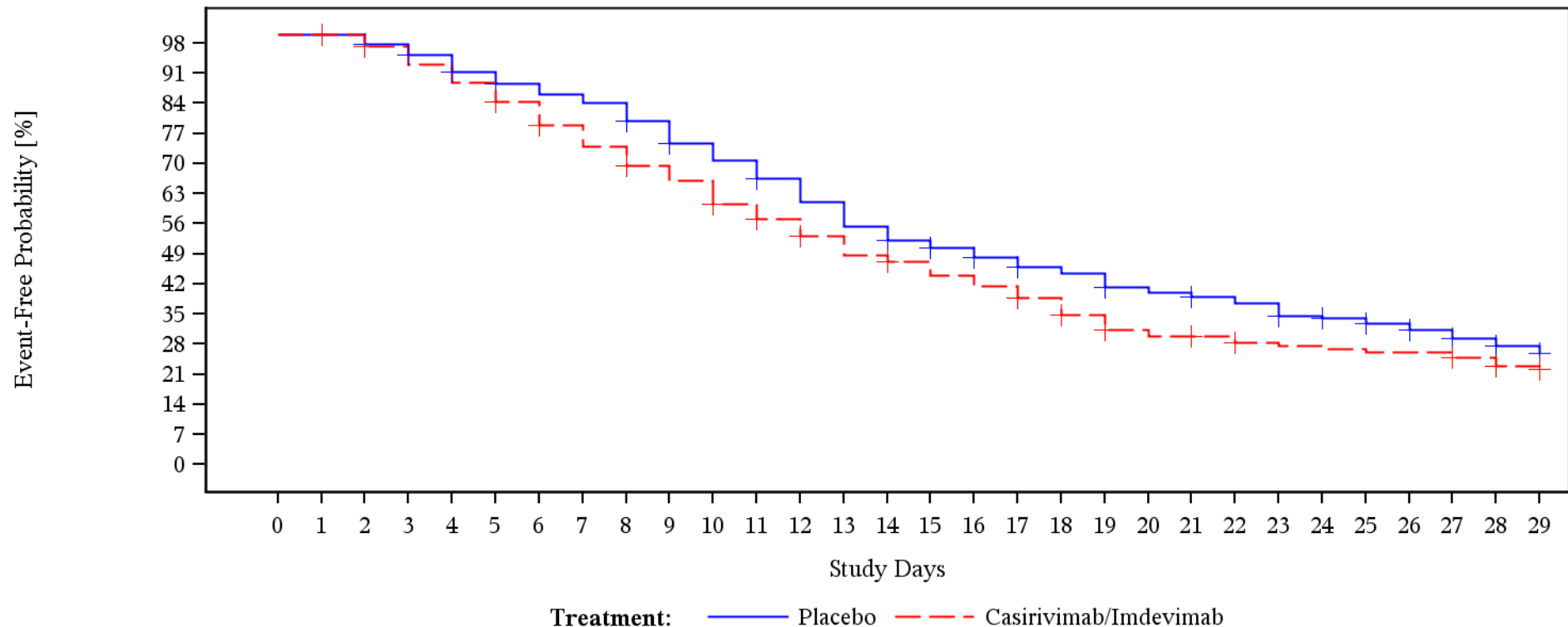
Placebo	352	352	232	222	215	203	195	187	177	168	152	145	135	128	121	113	107	96	91	86	86	82	75	74	72	69	66	60	54	38
Casirivimab/Imdevimab	364	364	247	236	219	198	183	169	157	136	121	108	100	93	85	79	73	69	65	61	55	53	53	52	48	46	44	44	39	26

Patients Censored

Placebo	0	120	123	123	124	124	124	126	126	127	128	128	128	129	129	129	129	130	131	131	131	132	132	132	132	132	132	135	138	153	189
Casirivimab/Imdevimab	0	117	117	118	119	119	120	120	121	122	122	122	122	123	124	125	125	125	126	126	127	127	128	130	130	130	130	133	143	169	

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

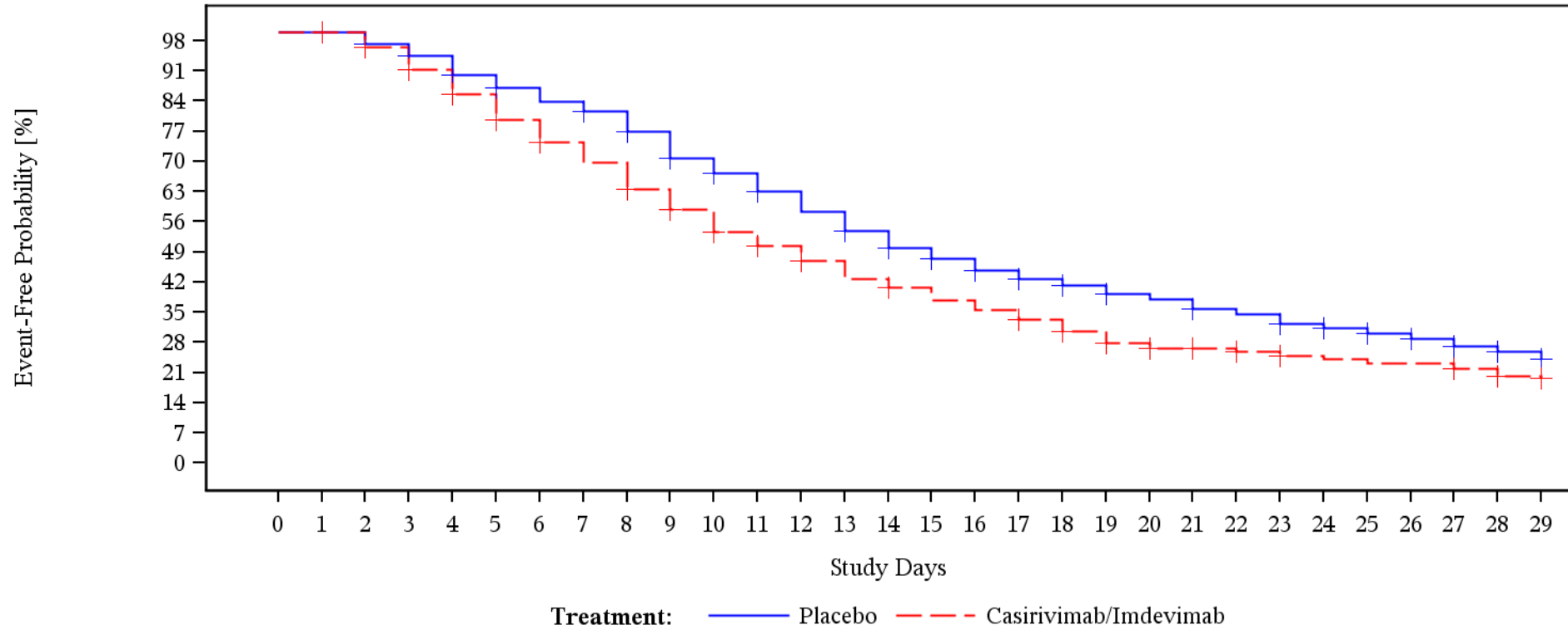
Placebo	396	396	301	291	281	268	255	248	242	228	211	200	187	172	156	145	139	131	124	120	110	107	103	99	90	88	84	78	69	48
Casirivimab/Imdevimab	372	372	287	278	266	254	240	224	210	196	186	170	159	146	134	129	120	113	105	93	83	79	77	72	70	68	66	66	61	32

Patients Censored

Placebo	0	95	98	101	102	107	107	107	109	111	111	112	112	112	114	115	117	118	118	119	119	120	120	121	122	123	125	129	146	191
Casirivimab/Imdevimab	0	85	86	86	86	87	88	88	89	89	90	91	93	93	94	94	94	95	96	97	97	99	100	100	100	100	100	102	126	157

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

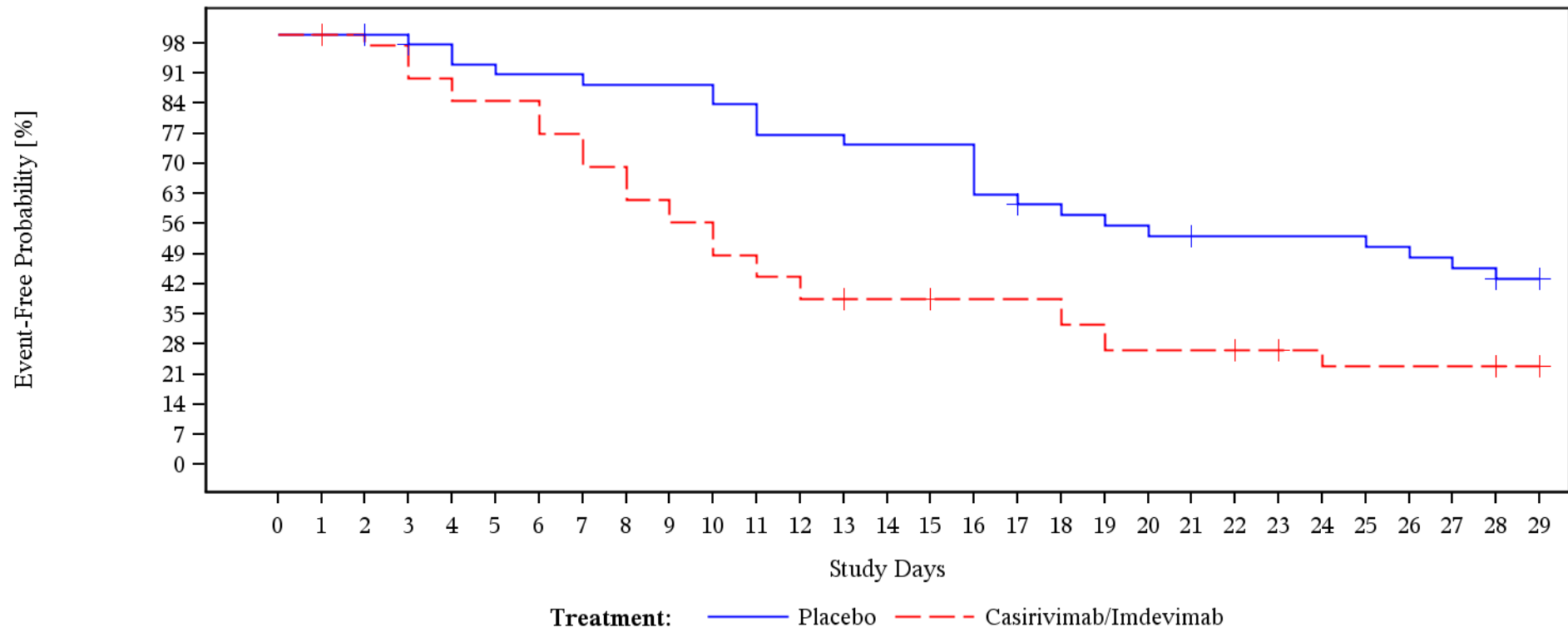
Placebo	660	660	474	457	443	420	401	387	374	351	320	304	284	262	241	222	210	196	186	178	169	163	153	148	137	132	126	115	102	69
Casirivimab/Imdevimab	643	643	477	459	434	405	376	350	328	296	273	248	232	214	195	184	171	160	149	135	122	116	114	109	104	101	97	97	87	50

Patients Censored

Placebo	0	186	190	191	193	198	198	200	202	204	205	206	206	207	209	210	212	213	214	215	215	216	216	217	218	219	224	230	259	323
Casirivimab/Imdevimab	0	166	167	168	169	170	172	172	174	175	176	177	179	179	181	181	181	182	184	185	186	188	189	190	190	190	190	195	225	274

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

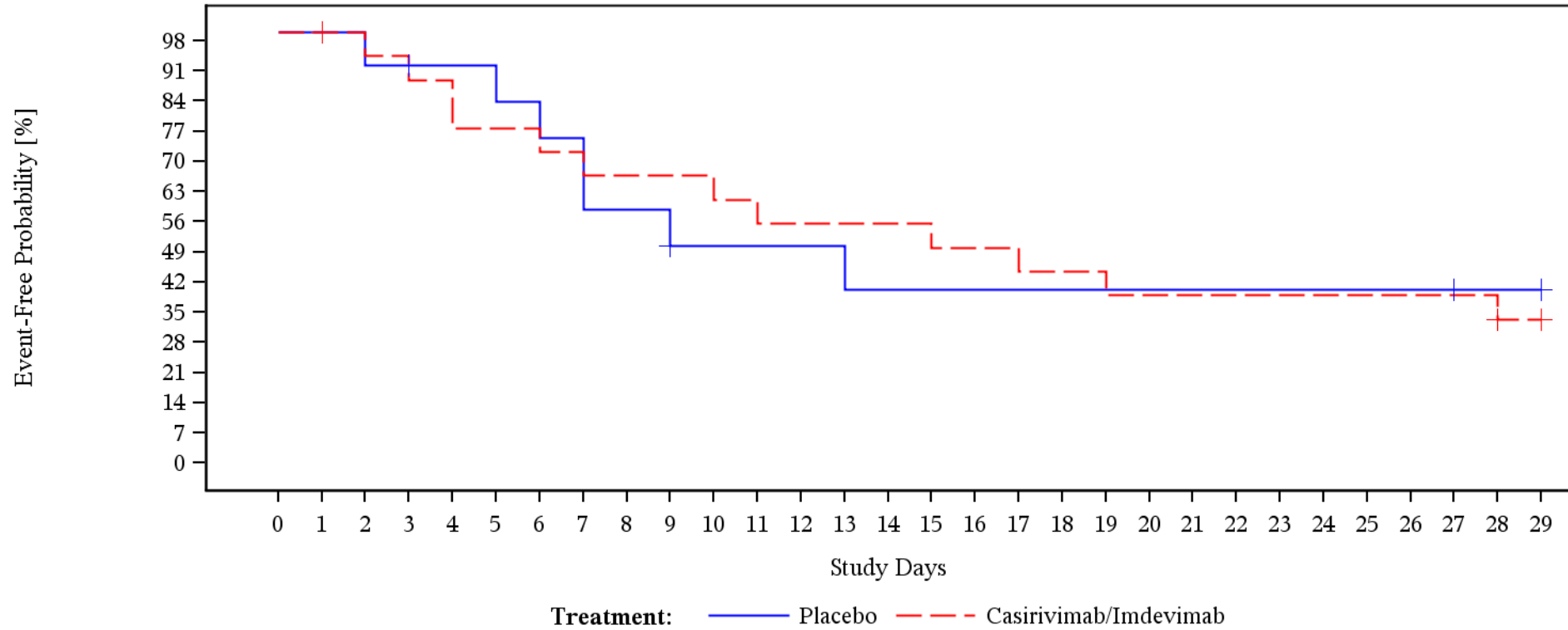
Placebo	68	68	46	44	42	40	39	39	38	38	38	36	33	33	32	32	32	27	25	24	23	22	21	21	21	21	20	19	18	14
Casirivimab/Imdevimab	62	62	39	38	35	33	33	30	27	24	22	19	17	15	14	14	13	13	13	11	9	9	9	8	7	6	6	6	6	3

Patients Censored

Placebo	0	22	24	25	25	25	25	25	25	25	25	25	25	25	25	25	25	26	26	26	26	27	27	27	27	27	27	27	27	30	44	
Casirivimab/Imdevimab	0	23	23	23	23	23	23	23	23	23	23	23	23	24	24	25	25	25	25	25	25	25	26	27	27	27	27	27	27	27	30	33

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

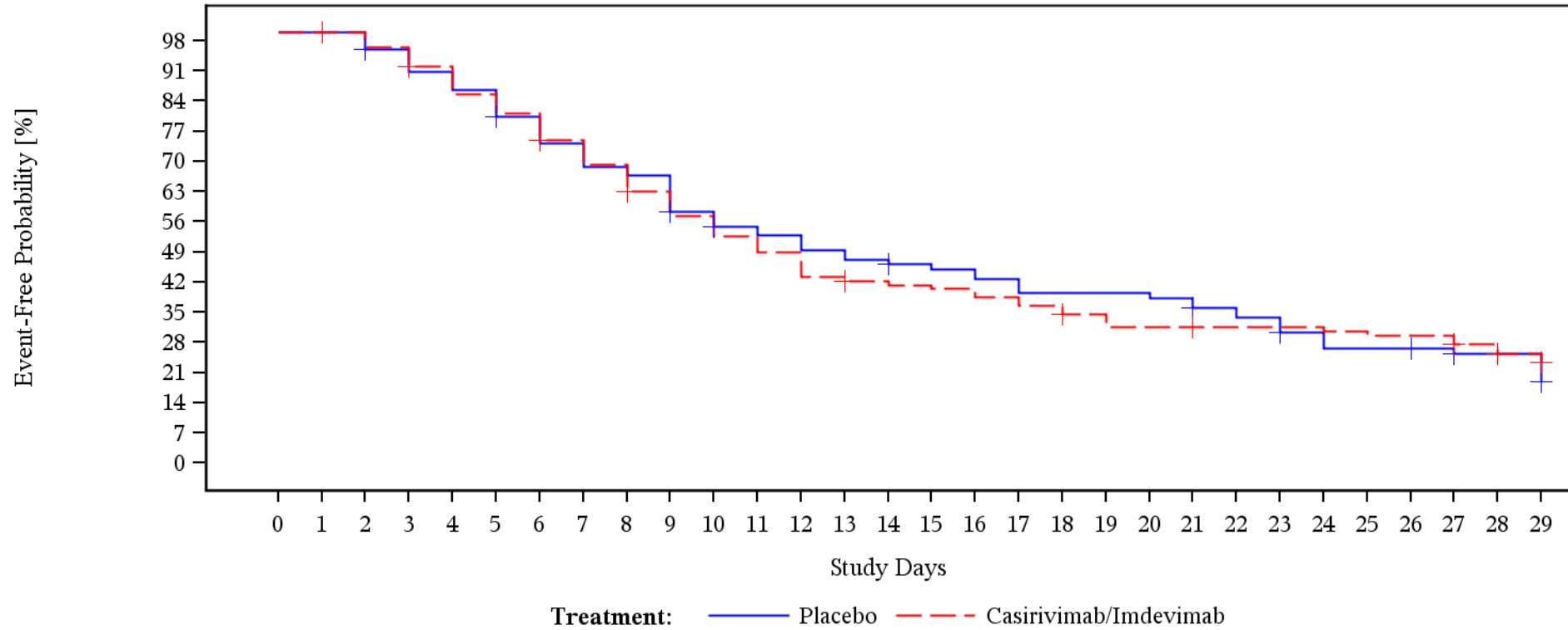
Placebo	20	20	13	12	11	11	10	9	7	7	5	5	5	5	4	4	4	4	4	4	4	4	4	4	4	3	3	
Casirivimab/Imdevimab	31	31	18	17	16	14	14	13	12	12	12	11	10	10	10	10	9	9	8	8	7	7	7	7	7	7	7	5

Patients Censored

Placebo	0	7	7	8	8	8	8	8	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	10	10	13	
Casirivimab/Imdevimab	0	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	14	19

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

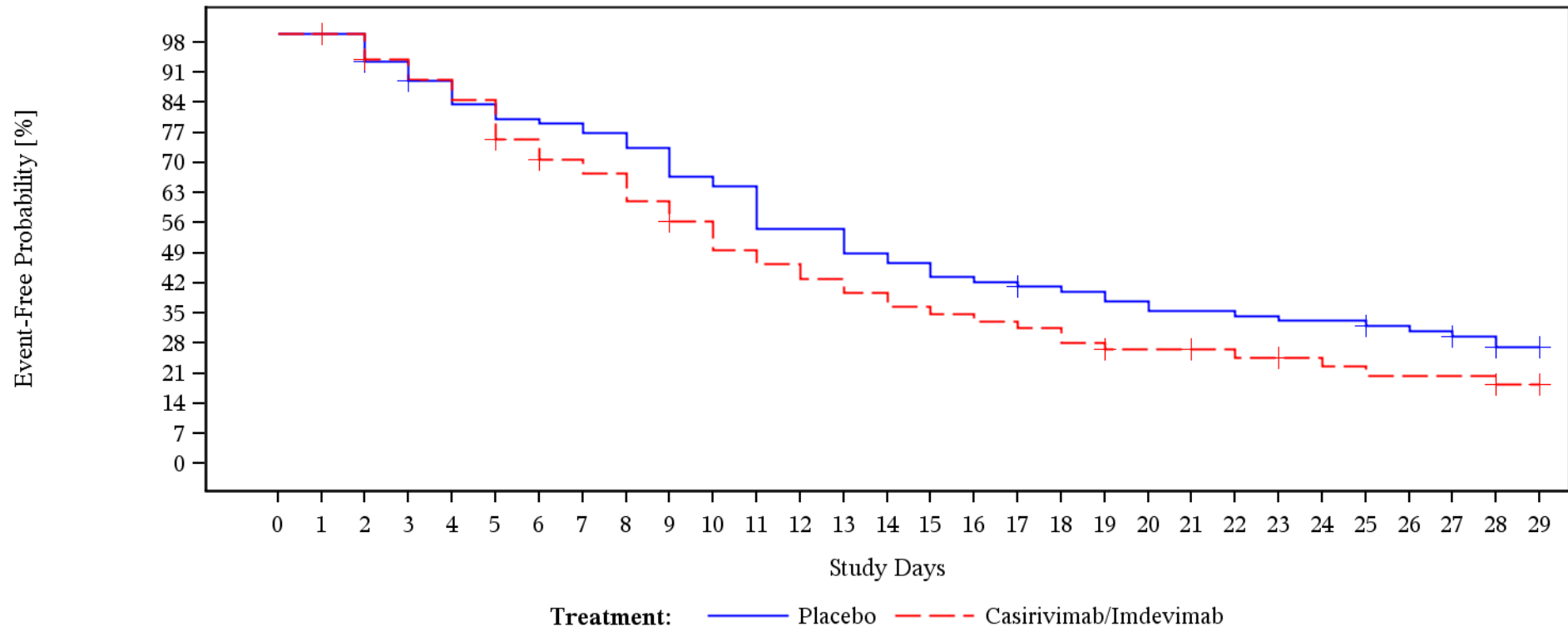
Placebo	150	150	98	93	88	84	76	70	65	63	54	50	48	45	43	41	40	38	35	35	35	34	31	29	25	22	22	20	18	16
Casirivimab/Imdevimab	161	161	112	108	102	95	90	82	76	67	61	56	52	46	44	43	42	40	38	35	32	32	31	31	31	30	29	29	24	13

Patients Censored

Placebo	0	52	53	53	53	55	55	55	55	56	57	57	57	57	58	58	58	58	58	58	58	58	59	59	60	60	60	62	63	65	77	
Casirivimab/Imdevimab	0	49	49	50	50	50	51	51	53	53	53	53	53	54	54	54	54	54	54	55	55	55	56	56	56	56	56	56	56	59	68	80

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

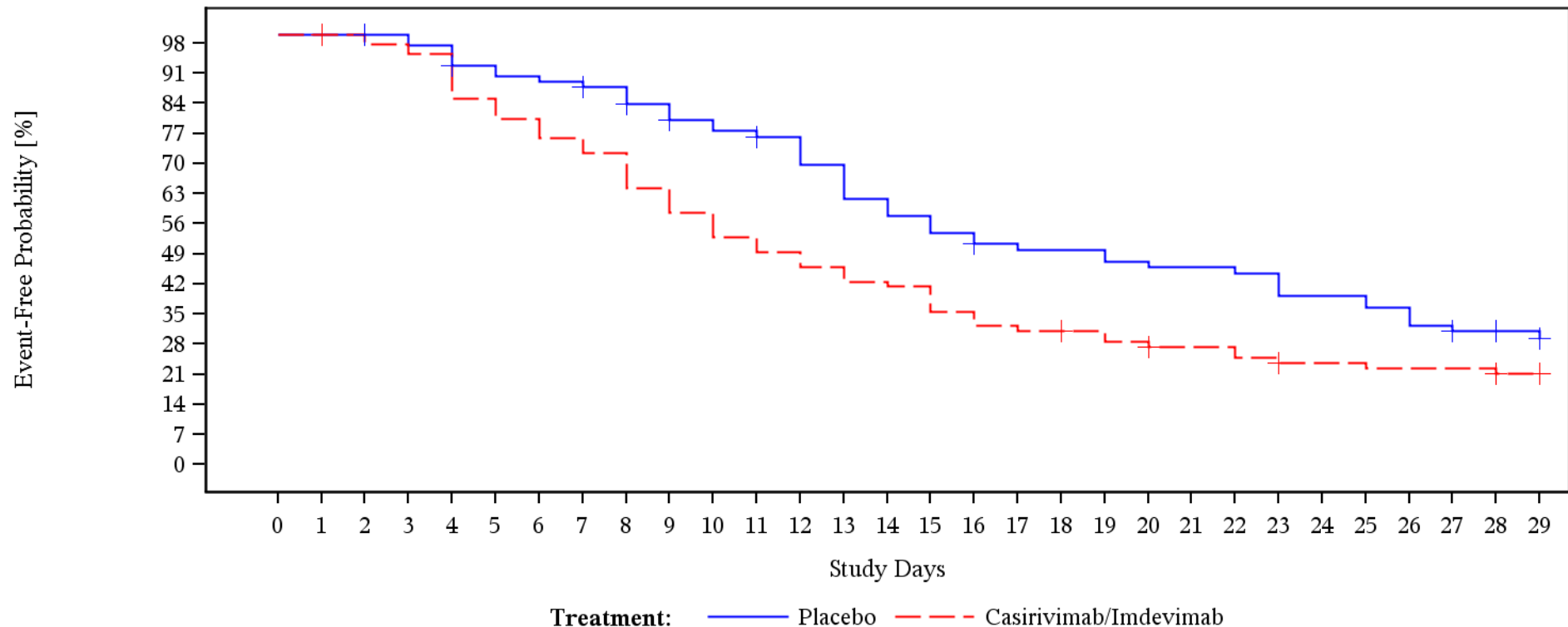
Placebo	123	123	92	85	80	75	72	71	69	66	60	58	49	49	44	42	39	38	36	35	33	31	31	30	29	29	27	26	24	10
Casirivimab/Imdevimab	91	91	66	61	58	55	48	44	42	38	34	30	28	26	24	22	21	20	19	17	15	15	14	13	12	11	10	10	10	7

Patients Censored

Placebo	0	31	32	33	33	33	33	33	33	33	33	33	33	33	33	33	33	34	34	34	34	34	34	34	34	35	35	36	48	58	
Casirivimab/Imdevimab	0	25	26	26	26	27	28	28	28	29	29	29	29	29	29	29	29	29	29	30	30	31	31	32	32	32	32	32	32	34	41

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

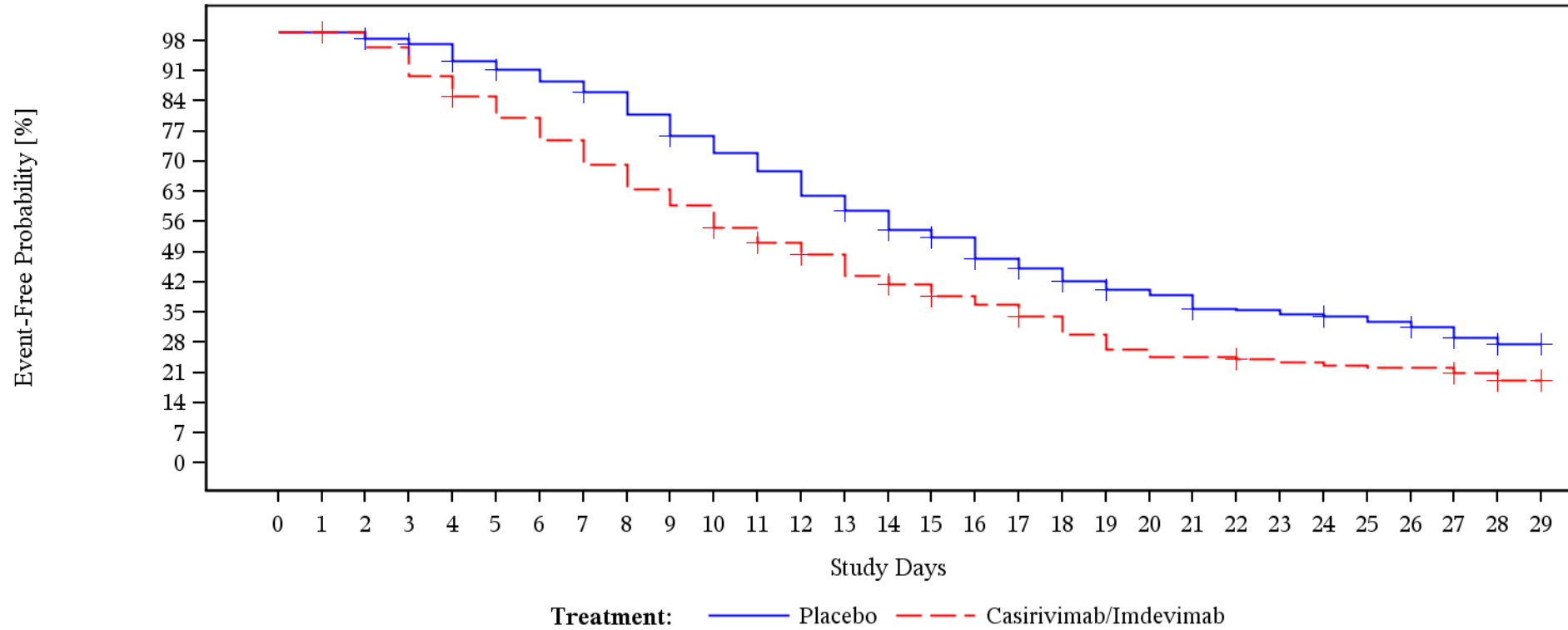
Placebo	125	125	84	82	80	75	73	72	70	66	62	60	58	53	47	44	41	38	37	37	35	34	34	33	29	29	27	24	20	18
Casirivimab/Imdevimab	119	119	87	85	83	74	70	66	63	56	51	46	43	40	37	36	31	28	27	26	24	22	22	20	18	18	17	17	17	10

Patients Censored

Placebo	0	41	43	43	44	44	44	45	46	47	47	48	48	48	48	48	49	49	49	49	49	49	49	49	49	49	49	52	54	71	
Casirivimab/Imdevimab	0	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	33	33	34	34	34	35	35	35	35	35	35	41	51

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

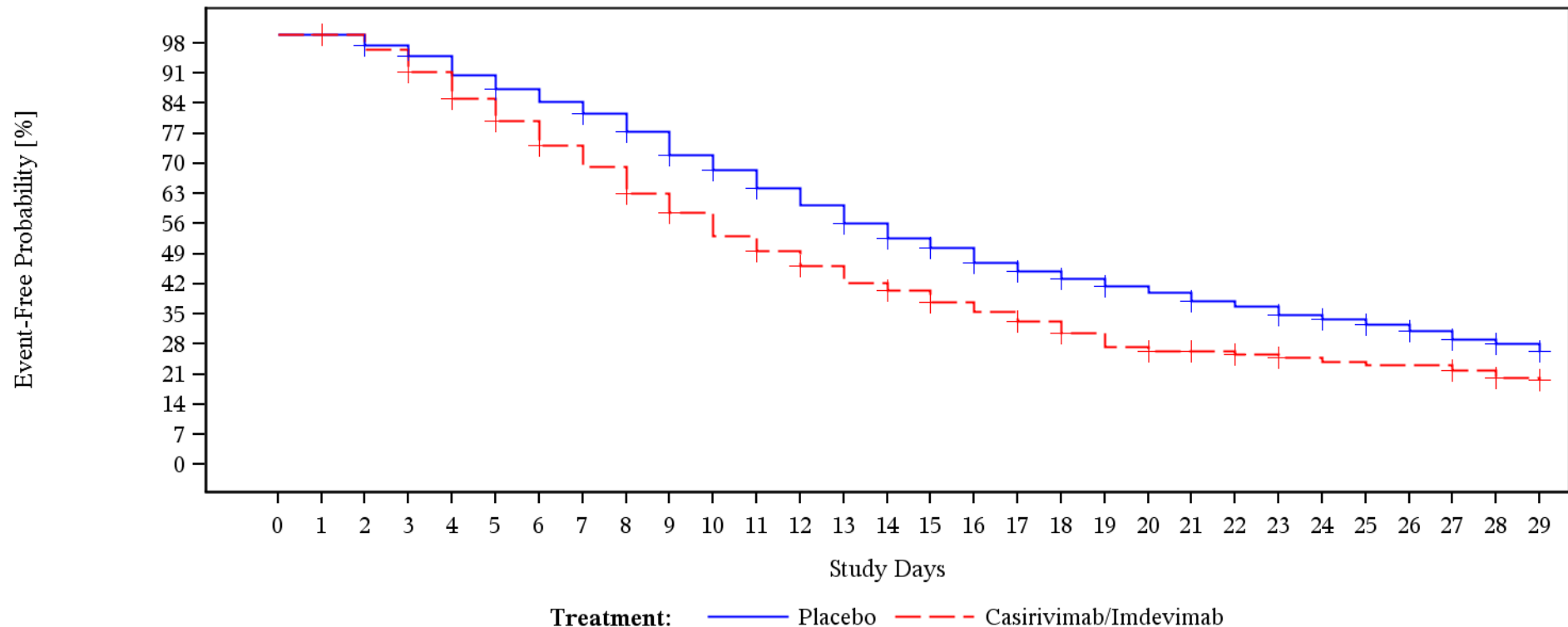
Placebo	346	346	257	251	246	235	227	220	213	200	187	177	167	153	143	131	126	113	107	99	93	90	82	81	79	77	74	68	61	42
Casirivimab/Imdevimab	363	363	267	258	240	226	213	199	184	169	159	144	134	125	112	105	97	92	84	74	65	61	61	58	56	54	53	53	48	28

Patients Censored

Placebo	0	89	91	93	94	97	97	98	98	99	99	99	99	100	101	102	103	104	105	106	106	107	107	107	108	108	111	113	129	171	
Casirivimab/Imdevimab	0	96	96	96	97	97	97	97	97	97	98	99	101	101	103	104	104	105	105	105	105	105	107	107	107	107	107	107	109	125	153

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

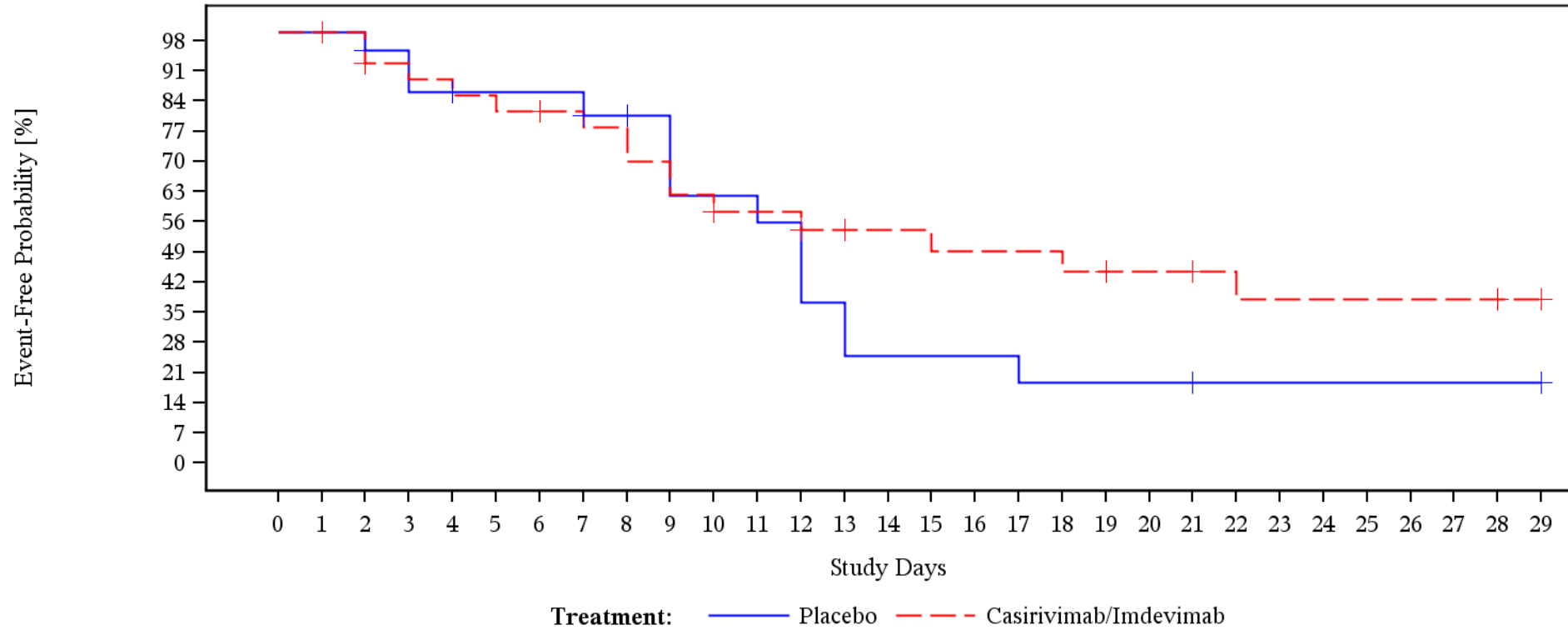
Placebo	711	711	510	493	478	455	434	419	405	383	353	335	313	294	273	254	242	223	212	203	193	186	176	171	160	155	148	136	121	84
Casirivimab/Imdevimab	698	698	506	489	461	429	401	372	347	314	291	264	245	227	208	197	183	172	160	145	130	124	123	118	112	108	104	104	94	56

Patients Censored

Placebo	0	201	205	208	208	213	213	214	215	218	219	220	220	221	223	224	226	228	229	230	230	231	231	232	233	234	239	246	278	357
Casirivimab/Imdevimab	0	192	192	193	194	195	196	196	198	199	199	200	201	201	203	204	204	205	207	207	208	209	211	213	213	213	213	218	248	303

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Country=MEX



Patients At Risk

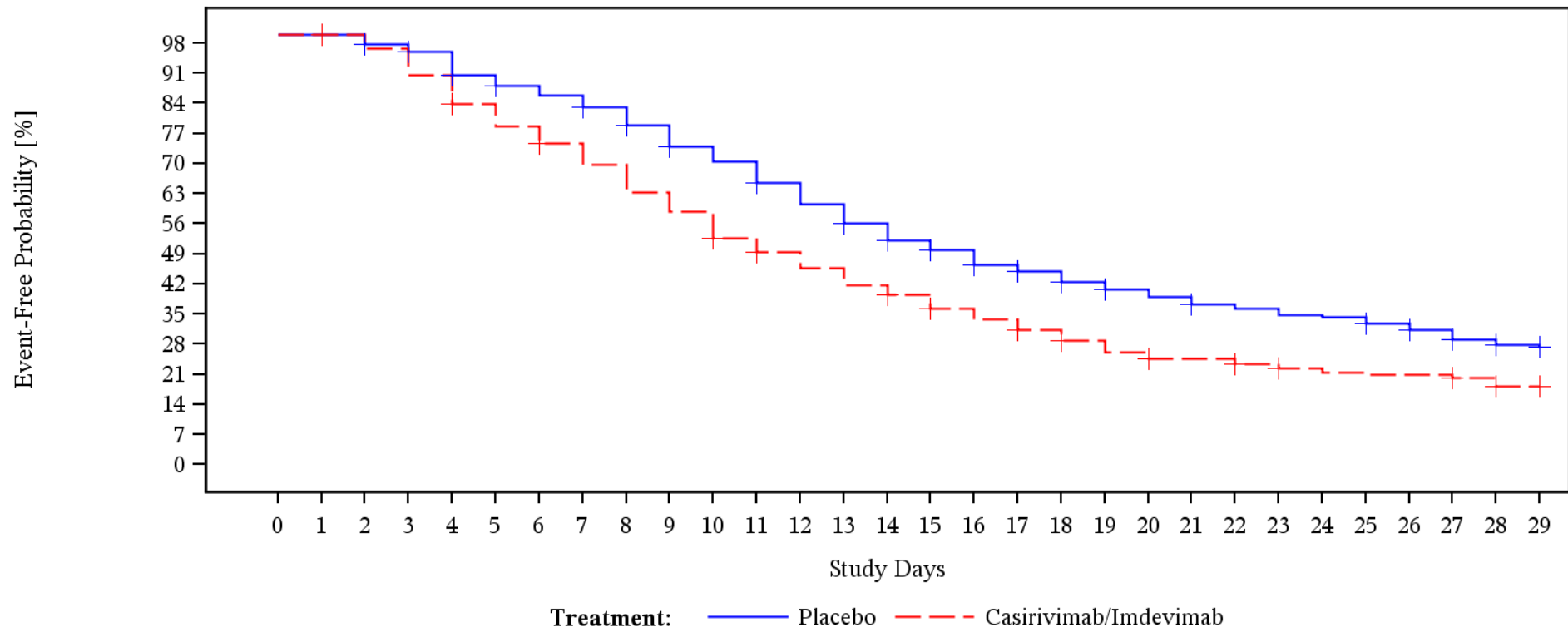
Placebo	37	37	23	20	18	16	16	16	14	13	10	10	9	6	4	4	4	4	3	3	3	3	2	2	2	2	2	2	2	2
Casirivimab/Imdevimab	38	38	28	25	24	23	22	21	20	18	16	14	14	12	11	11	10	10	10	9	8	8	7	6	6	6	6	6	6	2

Patients Censored

Placebo	0	14	16	16	18	18	18	19	20	20	20	20	20	20	20	20	20	20	20	20	20	21	21	21	21	21	21	21	21	23		
Casirivimab/Imdevimab	0	10	11	11	11	11	12	12	12	12	13	13	14	15	15	15	15	15	15	15	16	16	17	17	17	17	17	17	17	17	21	23

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

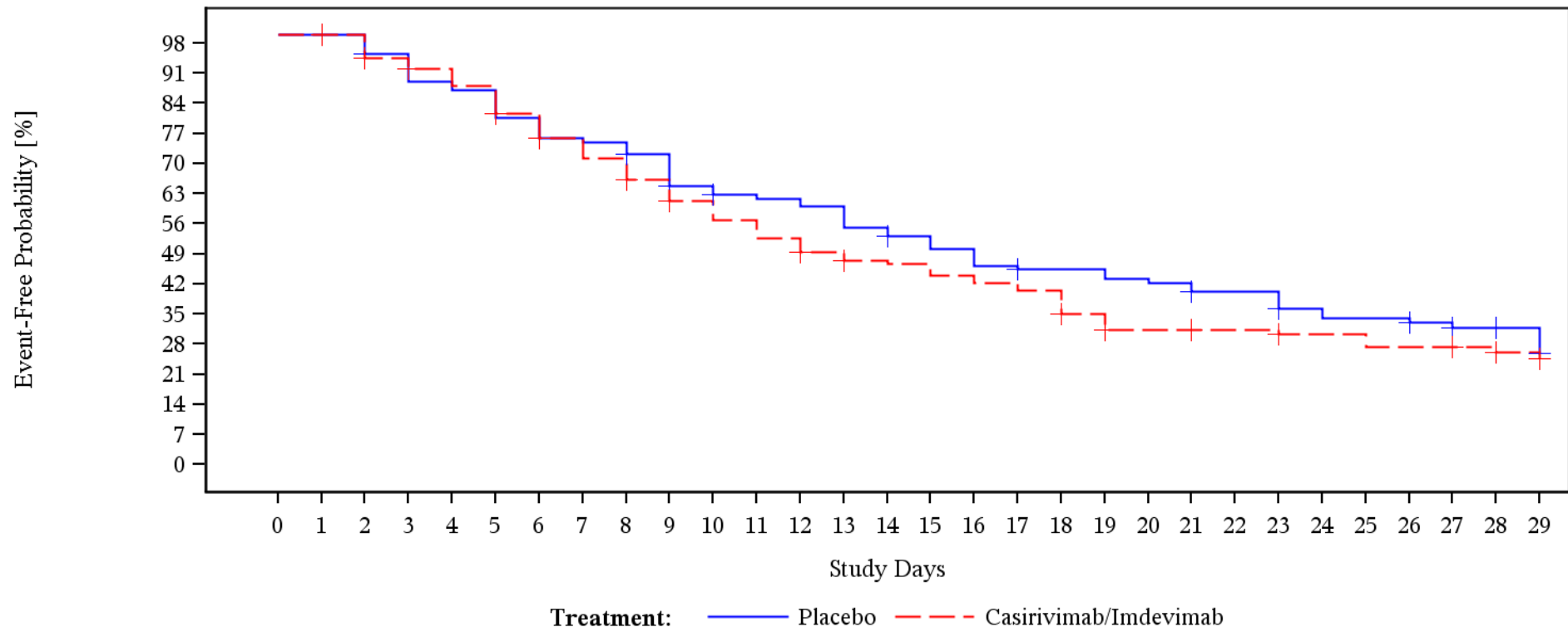
Placebo	519	519	377	365	355	333	320	312	300	284	264	251	233	215	198	183	174	160	154	145	138	132	125	122	117	115	109	100	88	59
Casirivimab/Imdevimab	500	500	367	355	332	307	288	272	254	231	214	191	178	165	150	140	128	119	109	100	90	84	84	78	74	70	69	69	64	36

Patients Censored

Placebo	0	142	146	149	151	155	155	157	158	160	160	161	161	162	163	164	166	167	168	169	169	170	170	170	170	171	175	180	205	263
Casirivimab/Imdevimab	0	133	133	133	134	134	135	135	135	135	136	137	137	137	139	140	140	141	142	142	143	143	145	146	146	146	146	148	170	206

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

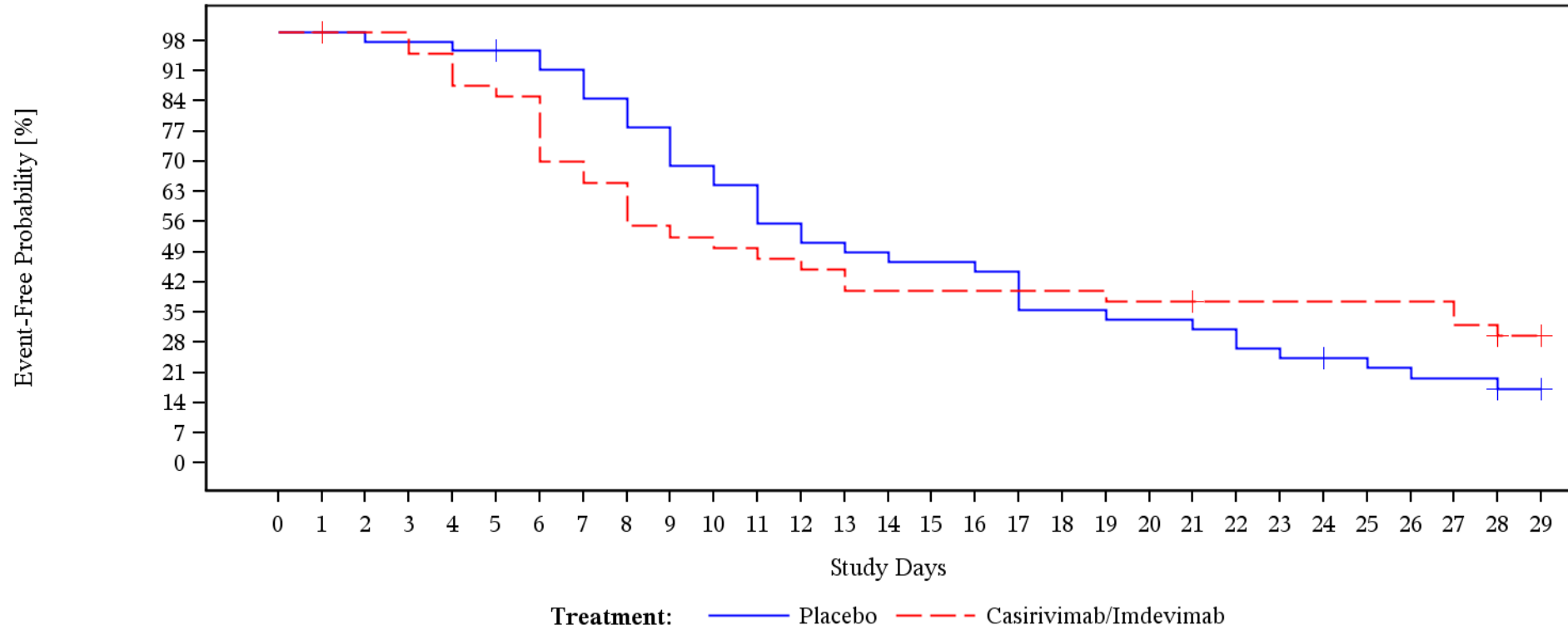
Placebo	164	164	110	103	96	94	87	82	81	77	68	65	64	62	57	54	51	47	45	45	43	42	39	39	34	32	32	30	27	21
Casirivimab/Imdevimab	177	177	127	119	115	110	101	93	87	79	72	67	62	56	53	52	49	47	45	38	33	33	32	32	30	30	27	27	24	17

Patients Censored

Placebo	0	54	56	56	56	56	56	56	57	58	59	59	59	59	60	60	60	61	61	61	61	62	62	63	63	63	64	66	72	89
Casirivimab/Imdevimab	0	50	51	52	52	53	54	54	56	57	57	57	59	60	60	60	60	61	62	62	63	63	64	64	64	64	64	67	73	89

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	65	65	46	45	45	44	43	41	38	35	31	29	25	23	22	21	21	20	16	16	15	15	14	12	11	10	9	8	8	6
Casirivimab/Imdevimab	59	59	40	40	38	35	34	28	26	22	21	20	19	18	16	16	16	16	16	16	15	15	14	14	14	14	14	14	12	5

Patients Censored

Placebo	0	19	19	19	19	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	21	21	21	21	22	28	
Casirivimab/Imdevimab	0	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	20	20	20	20	20	20	20	20	26	31

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: mFAS
 ENDPOINT: Time to COVID-19 symptoms resolution
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												log-rank p-value	Casirivimab/Imdevimab vs. Placebo			Interaction Test p-value (likelihood ratio)	
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event							Hazard Ratio				
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status (GCONV=1E-8)
All	n/a	736	100,0	410	55,7	326	44,3	6,00	6,00	7,00	11,00	10,00	13,00	748	100,0	368	49,2	380	50,8	9,00	8,00	10,00	15,00	14,00	17,00	0,0001	1,31	1,14	1,51	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	364	49,5	195	53,6	169	46,4	5,00	5,00	6,00	10,00	8,00	11,00	352	47,1	163	46,3	189	53,7	8,00	7,00	9,00	15,00	13,00	16,00	0,0004	1,44	1,17	1,77	Convergence criterion (GCONV=1E-8) satisfied.	0,1843
	Female	372	50,5	215	57,8	157	42,2	7,00	6,00	8,00	13,00	12,00	15,00	396	52,9	205	51,8	191	48,2	9,00	8,00	11,00	16,00	13,00	19,00	0,0439	1,21	1,00	1,47	Convergence criterion (GCONV=1E-8) satisfied.	
Age	18-64	643	87,4	369	57,4	274	42,6	6,00	6,00	7,00	12,00	10,00	13,00	660	88,2	337	51,1	323	48,9	9,00	8,00	9,00	14,00	13,00	16,00	0,0010	1,27	1,10	1,47	Convergence criterion (GCONV=1E-8) satisfied.	0,1635
	65-74	62	8,4	29	46,8	33	53,2	7,00	3,00	8,00	10,00	8,00	18,00	68	9,1	24	35,3	44	64,7	13,00	7,00	17,00	26,00	16,00	NE	0,0051	2,12	1,22	3,66	Convergence criterion (GCONV=1E-8) satisfied.	
	>=75	31	4,2	12	38,7	19	61,3	6,00	2,00	11,00	16,00	6,00	NE	20	2,7	7	35,0	13	65,0	7,00	2,00	9,00	13,00	5,00	NE	0,9602	1,02	0,40	2,61	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline viral load categories	<=10^5 copies/mL	161	21,9	81	50,3	80	49,7	6,00	5,00	8,00	11,00	9,00	15,00	150	20,1	73	48,7	77	51,3	6,00	5,00	9,00	12,00	9,00	17,00	0,9762	1,00	0,73	1,37	Convergence criterion (GCONV=1E-8) satisfied.	0,2735
	>10^5 copies/mL - <=10^6 copies/mL	91	12,4	50	54,9	41	45,1	6,00	4,00	8,00	10,00	8,00	14,00	123	16,4	65	52,8	58	47,2	8,00	4,00	10,00	13,00	11,00	18,00	0,1310	1,32	0,91	1,91	Convergence criterion (GCONV=1E-8) satisfied.	
	>10^6 copies/mL - <=10^7 copies/mL	119	16,2	68	57,1	51	42,9	7,00	5,00	8,00	11,00	9,00	15,00	125	16,7	54	43,2	71	56,8	12,00	8,00	13,00	17,00	14,00	23,00	0,0149	1,54	1,07	2,20	Convergence criterion (GCONV=1E-8) satisfied.	
	>10^7 copies/mL	363	49,3	210	57,9	153	42,1	6,00	5,00	7,00	12,00	10,00	13,00	346	46,3	175	50,6	171	49,4	10,00	9,00	11,00	16,00	14,00	18,00	0,0004	1,42	1,16	1,73	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	2	0,3	1	50,0	1	50,0	23,00	23,00	NE	NE	23,00	NE	4	0,5	1	25,0	3	75,0	9,00	NE	NE	9,00	NE	NE	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Country	USA	698	94,8	395	56,6	303	43,4	6,00	6,00	7,00	11,00	10,00	13,00	711	95,1	354	49,8	357	50,2	9,00	8,00	10,00	16,00	14,00	17,00	<.0001	1,35	1,17	1,56	Convergence criterion (GCONV=1E-8) satisfied.	0,0498
	MEX	38	5,2	15	39,5	23	60,5	8,00	2,00	10,00	15,00	8,00	NE	37	4,9	14	37,8	23	62,2	9,00	2,00	12,00	12,00	9,00	13,00	0,2939	0,68	0,33	1,43	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline serostatus	Negative	500	67,9	294	58,8	206	41,2	6,00	5,00	7,00	11,00	10,00	13,00	519	69,4	256	49,3	263	50,7	9,00	8,00	10,00	15,00	14,00	17,00	<.0001	1,43	1,21	1,69	Convergence criterion (GCONV=1E-8) satisfied.	0,1597
	Positive	177	24,0	88	49,7	89	50,3	7,00	5,00	8,00	12,00	10,00	17,00	164	21,9	75	45,7	89	54,3	8,00	5,00	9,00	16,00	13,00	21,00	0,3935	1,14	0,84	1,55	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	59	8,0	28	47,5	31	52,5	6,00	4,00	8,00	10,50	7,00	27,00	65	8,7	37	56,9	28	43,1	9,00	7,00	11,00	13,00	10,00	17,00	0,7532	0,93	0,57	1,52	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-1-eff-tte-tsres

Datenschnitt 18.02.2021 (DCO1)

Wirksamkeit

PRO

POPULATION: mFAS
 ENDPOINT: EQ-5D-5L VAS
 MODEL: --
 STUDY: R10933-10987-COV-2067
 Template Compliance/Mean

		Casirivimab/Imdevimab (N=736)						Placebo (N=748)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
Visit													
All													
Baseline	All	221	30,0	221	100,0	65,66	18,94	229	30,6	229	100,0	66,03	18,83
Day 2	All	221	30,0	196	88,7	68,37	17,92	229	30,6	206	90,0	67,53	19,13
Day 3	All	221	30,0	199	90,0	73,11	15,43	229	30,6	203	88,6	71,02	18,00
Day 4	All	221	30,0	193	87,3	74,93	16,27	229	30,6	202	88,2	72,84	18,42
Day 5	All	220	29,9	186	84,5	78,28	15,27	229	30,6	196	85,6	74,65	17,50
Day 6	All	220	29,9	187	85,0	80,50	13,99	229	30,6	193	84,3	76,54	17,11
Day 7	All	220	29,9	149	67,7	82,35	12,09	229	30,6	139	60,7	78,88	14,41
Day 8	All	220	29,9	181	82,3	83,31	14,67	229	30,6	186	81,2	80,49	15,97
Day 9	All	220	29,9	180	81,8	84,26	12,92	229	30,6	182	79,5	82,56	14,03
Day 10	All	220	29,9	182	82,7	86,34	13,64	229	30,6	176	76,9	83,40	15,06
Day 11	All	220	29,9	181	82,3	87,19	13,98	229	30,6	180	78,6	84,50	13,69
Day 12	All	220	29,9	176	80,0	87,43	13,26	229	30,6	181	79,0	86,01	12,68
Day 13	All	220	29,9	178	80,9	87,30	14,21	229	30,6	182	79,5	86,90	12,44
Day 14	All	220	29,9	188	85,5	88,65	12,38	229	30,6	188	82,1	87,97	11,94
Day 15	All	220	29,9	110	50,0	89,44	12,26	229	30,6	118	51,5	89,11	11,09
Day 16	All	220	29,9	177	80,5	89,44	12,79	229	30,6	173	75,5	88,05	11,83
Day 17	All	220	29,9	173	78,6	90,24	12,29	229	30,6	184	80,3	89,02	11,45
Day 18	All	220	29,9	173	78,6	90,61	11,62	229	30,6	168	73,4	90,34	10,41
Day 19	All	219	29,8	181	82,6	89,99	12,58	229	30,6	172	75,1	90,08	10,63
Day 20	All	219	29,8	174	79,5	90,74	12,42	229	30,6	184	80,3	89,90	11,20
Day 21	All	219	29,8	176	80,4	90,41	13,11	229	30,6	176	76,9	89,85	11,45
Day 22	All	219	29,8	173	79,0	91,20	12,32	228	30,5	169	74,1	90,25	11,58
Day 23	All	219	29,8	172	78,5	91,22	12,34	228	30,5	166	72,8	90,49	11,01
Day 24	All	219	29,8	168	76,7	91,11	12,71	228	30,5	165	72,4	90,61	10,61
Day 25	All	219	29,8	163	74,4	92,24	10,81	228	30,5	177	77,6	90,76	10,74
Day 26	All	219	29,8	167	76,3	91,65	11,45	228	30,5	170	74,6	91,18	10,98
Day 27	All	219	29,8	158	72,1	92,39	10,51	228	30,5	162	71,1	91,29	10,37
Day 28	All	219	29,8	163	74,4	92,26	10,70	228	30,5	160	70,2	91,58	10,07
Day 29	All	219	29,8	92	42,0	92,97	9,44	228	30,5	101	44,3	92,34	8,87
Day 30	All	219	29,8	0	0,0			228	30,5	1	0,4	96,00	0,00

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 18Feb2021

Program: t-eff-mean.sas

Output: t14-2-eff-mean-overall-eq5d0206-eq5dbl.xlsx, t14-2-eff-mean-overall-eq5d0206-eq5dbl.pdf

POPULATION: PRO Evaluable (mFAS)
 ENDPOINT: EQ-5D-5L VAS
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Change from Baseline in EQ5D02-EQ VAS Score (Analysis of MMRM)

Endpoint	Name	Level	Casirivimab/Imdevimab					Placebo					Difference between Treatments (Casirivimab/Imdevimab vs. Placebo)					
			N			Statistics		N			Statistics		LSMeans ³	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/Method ⁴	
			Total	with baseline value	included in analysis ¹	LSMeans ²	SE (LSMeans)	Total	with baseline value	included in analysis ¹	LSMeans ²	SE (LSMeans)						
Change from Baseline in EQ5D02-EQ VAS Score	All	Day 29	730	201	201	25,97	0,77	738	206	206	25,45	0,76	0,52	1,08	-1,60	2,64	MFAS	adjusted

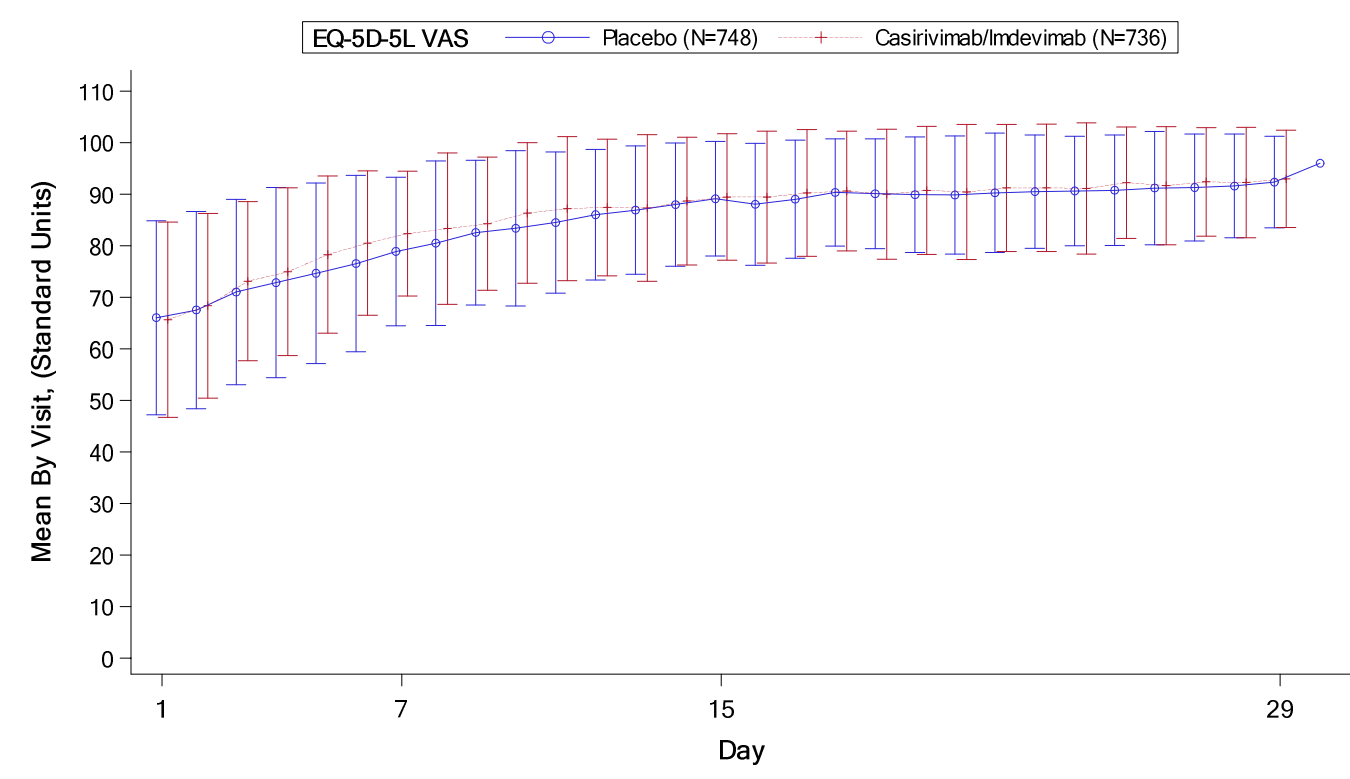
footnotes:

- 1) Patients with a value at baseline and at least one post-baseline value
- 2) LSMeans of change from baseline from MMRM (including all available records from all visits)
- 3) Contrasts from MMRM
- 4) Factors/Covariates: treatment, country, visit, treatment-by-visit interaction, baseline value. In addition, for the **total population**, adjusted for randomization stratification factors: country. Data as observed (no imputation of missing values)
Covariance matrix: unstructured

Test for interaction based on Likelihood-Ratio test
 Clinical cut-off: 18Feb2021

Program: t-eff-mmrn.sas
 Output: t15-eff-mmrn-overall-eq5d0206.xlsx, t15-eff-mmrn-overall-eq5d0206.pdf

Figure 2.2. Line plot of mean of EQ5D02-EQ VAS Score at each visit
Modified Full Analysis Set



Clinical cut-off: 18Feb2021

POPULATION: mFAS

ENDPOINT: Return to usual health

MODEL: --

STUDY: R10933-10987-COV-2067

Template Compliance/Mean

		Casirivimab/Imdevimab (N=736)						Placebo (N=748)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
Visit													
All													
Baseline	All	409	55,6	409	100,0			416	55,6	416	100,0		
Day 2	All	409	55,6	365	89,2			416	55,6	370	88,9		
Day 3	All	409	55,6	366	89,5			416	55,6	368	88,5		
Day 4	All	408	55,4	354	86,8			416	55,6	361	86,8		
Day 5	All	407	55,3	344	84,5			416	55,6	355	85,3		
Day 6	All	407	55,3	345	84,8			416	55,6	349	83,9		
Day 7	All	407	55,3	291	71,5			416	55,6	288	69,2		
Day 8	All	407	55,3	326	80,1			416	55,6	339	81,5		
Day 9	All	407	55,3	327	80,3			416	55,6	321	77,2		
Day 10	All	407	55,3	330	81,1			416	55,6	323	77,6		
Day 11	All	407	55,3	326	80,1			415	55,5	324	78,1		
Day 12	All	407	55,3	321	78,9			415	55,5	320	77,1		
Day 13	All	407	55,3	320	78,6			415	55,5	318	76,6		
Day 14	All	407	55,3	337	82,8			415	55,5	320	77,1		
Day 15	All	407	55,3	225	55,3			415	55,5	232	55,9		
Day 16	All	407	55,3	314	77,1			415	55,5	310	74,7		
Day 17	All	407	55,3	309	75,9			415	55,5	316	76,1		
Day 18	All	407	55,3	313	76,9			415	55,5	295	71,1		
Day 19	All	406	55,2	321	79,1			415	55,5	308	74,2		
Day 20	All	406	55,2	315	77,6			415	55,5	321	77,3		
Day 21	All	406	55,2	312	76,8			415	55,5	308	74,2		
Day 22	All	406	55,2	319	78,6			414	55,3	298	72,0		
Day 23	All	406	55,2	309	76,1			414	55,3	295	71,3		
Day 24	All	406	55,2	305	75,1			414	55,3	293	70,8		
Day 25	All	406	55,2	291	71,7			414	55,3	300	72,5		
Day 26	All	406	55,2	297	73,2			414	55,3	290	70,0		
Day 27	All	406	55,2	288	70,9			413	55,2	300	72,6		
Day 28	All	406	55,2	290	71,4			412	55,1	284	68,9		
Day 29	All	406	55,2	176	43,3			412	55,1	181	43,9		
Day 30	All	406	55,2	1	0,2			412	55,1	2	0,5		

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 18Feb2021

Program: t-eff-mean-update.sas

Output: t14-3-eff-mean-overall-precol9h.xlsx, t14-3-eff-mean-overall-precol9h.pdf

POPULATION: mFAS
 ENDPOINT: Return to usual activities
 MODEL: --
 STUDY: R10933-10987-COV-2067
 Template Compliance/Mean

		Casirivimab/Imdevimab (N=736)						Placebo (N=748)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
All													
Baseline	All	410	55,7	410	100,0			416	55,6	416	100,0		
Day 2	All	410	55,7	363	88,5			416	55,6	370	88,9		
Day 3	All	410	55,7	366	89,3			416	55,6	368	88,5		
Day 4	All	409	55,6	358	87,5			416	55,6	361	86,8		
Day 5	All	408	55,4	344	84,3			416	55,6	355	85,3		
Day 6	All	408	55,4	346	84,8			416	55,6	349	83,9		
Day 7	All	408	55,4	289	70,8			416	55,6	288	69,2		
Day 8	All	408	55,4	326	79,9			416	55,6	336	80,8		
Day 9	All	408	55,4	329	80,6			416	55,6	324	77,9		
Day 10	All	408	55,4	327	80,1			416	55,6	320	76,9		
Day 11	All	408	55,4	330	80,9			415	55,5	329	79,3		
Day 12	All	408	55,4	317	77,7			415	55,5	320	77,1		
Day 13	All	408	55,4	318	77,9			415	55,5	322	77,6		
Day 14	All	408	55,4	332	81,4			415	55,5	322	77,6		
Day 15	All	408	55,4	223	54,7			415	55,5	234	56,4		
Day 16	All	408	55,4	315	77,2			415	55,5	310	74,7		
Day 17	All	408	55,4	308	75,5			415	55,5	313	75,4		
Day 18	All	408	55,4	312	76,5			415	55,5	298	71,8		
Day 19	All	407	55,3	320	78,6			415	55,5	305	73,5		
Day 20	All	407	55,3	314	77,1			415	55,5	322	77,6		
Day 21	All	407	55,3	315	77,4			415	55,5	300	72,3		
Day 22	All	407	55,3	316	77,6			414	55,3	299	72,2		
Day 23	All	407	55,3	309	75,9			414	55,3	298	72,0		
Day 24	All	407	55,3	306	75,2			414	55,3	293	70,8		
Day 25	All	407	55,3	294	72,2			414	55,3	302	72,9		
Day 26	All	407	55,3	298	73,2			414	55,3	289	69,8		
Day 27	All	407	55,3	289	71,0			413	55,2	295	71,4		
Day 28	All	407	55,3	291	71,5			412	55,1	285	69,2		
Day 29	All	407	55,3	177	43,5			412	55,1	182	44,2		
Day 30	All	407	55,3	1	0,2			412	55,1	2	0,5		

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

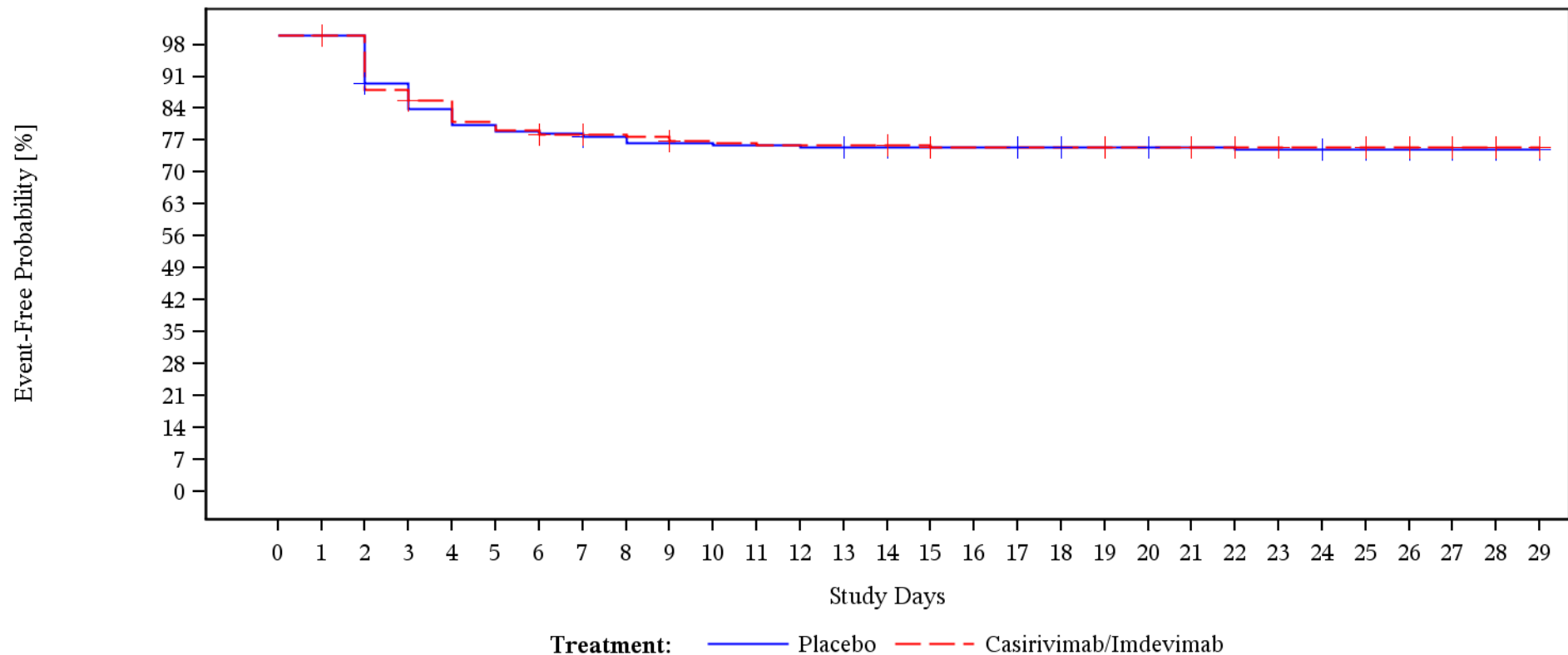
² mean: descriptive statistics - absolute values

Clinical cut-off: 18Feb2021

Program: t-eff-mean-update.sas

Output: t14-4-eff-mean-overall-precol9a.xlsx, t14-4-eff-mean-overall-precol9a.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first deterioration
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	226	199	187	179	176	175	171	168	168	167	167	166	165	163	162	162	161	160	159	156	155	154	154	152	146	138	129	72
Casirivimab/Imdevimab	736	736	217	191	185	175	171	167	166	165	162	161	160	160	160	159	157	157	157	157	155	155	154	153	149	149	147	141	134	70

Patients Censored

Placebo	0	522	525	525	525	525	525	527	527	527	527	527	527	528	530	531	531	532	533	534	537	538	538	538	540	546	554	563	620	692
Casirivimab/Imdevimab	0	519	519	520	520	520	522	523	523	524	524	524	524	524	525	526	526	526	526	528	528	529	530	534	534	536	542	549	613	683

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-2-km-plot-ttdet10.pdf

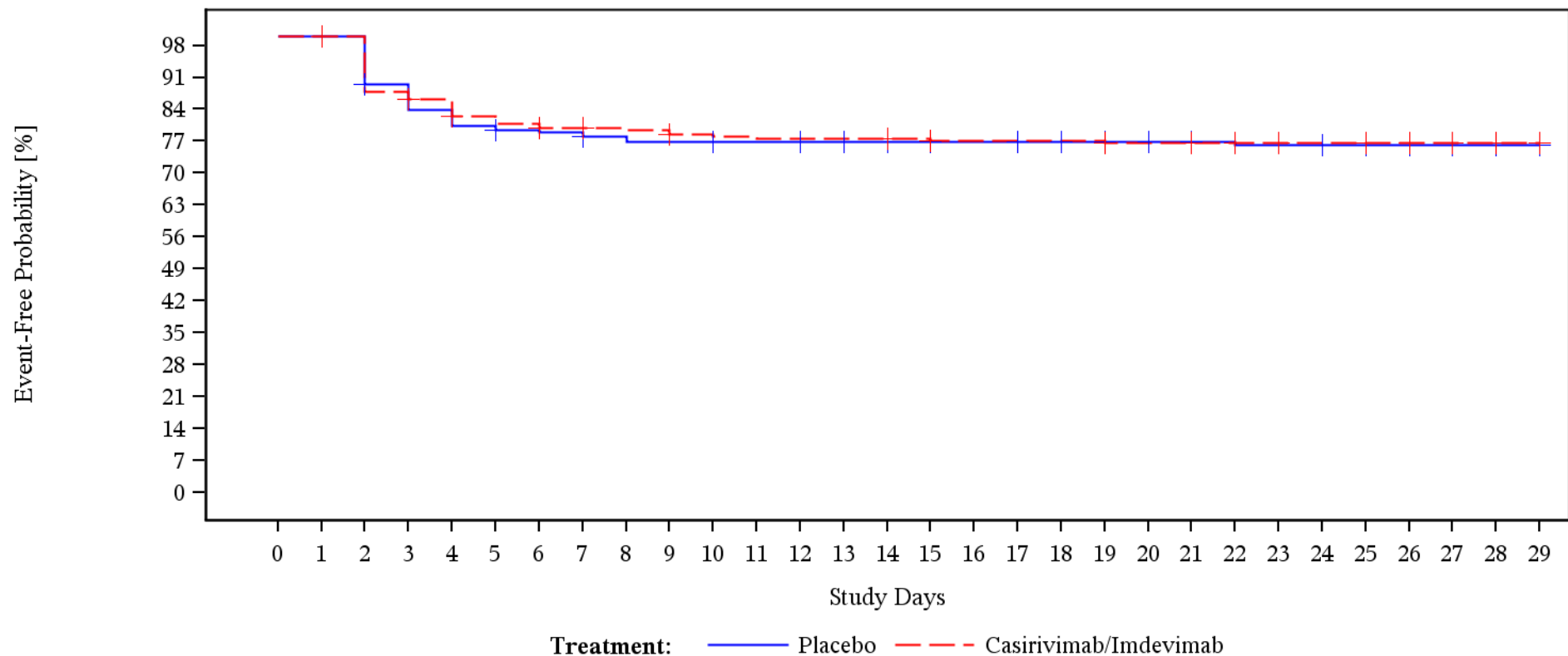
POPULATION: mFAS
 ENDPOINT: Time to first deterioration (MID=10)
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	53	7,2	683	92,8	NE	5,00	NE	NE	NE	NE	740	100,0	56	7,5	692	92,5	22,00	4,00	NE	NE	NE	NE	0,9052	0,98	0,67	1,42	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-2-eff-tte-ttdet10

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first deterioration - Sensitivity Analysis
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	226	199	187	179	176	175	171	168	168	167	167	166	165	163	162	162	161	160	159	156	155	154	154	152	146	138	129	72
Casirivimab/Imdevimab	736	736	216	190	184	175	172	168	167	166	163	162	161	161	161	160	158	158	158	158	155	155	154	153	149	149	147	141	134	70

Patients Censored

Placebo	0	522	525	525	525	526	526	528	528	528	529	529	530	531	533	534	534	535	536	537	540	541	541	541	543	549	557	566	623	695
Casirivimab/Imdevimab	0	520	520	522	523	523	525	526	526	527	527	527	527	527	528	529	529	529	529	531	531	532	533	537	537	539	545	552	616	686

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-3-km-plot-ttdets10.pdf

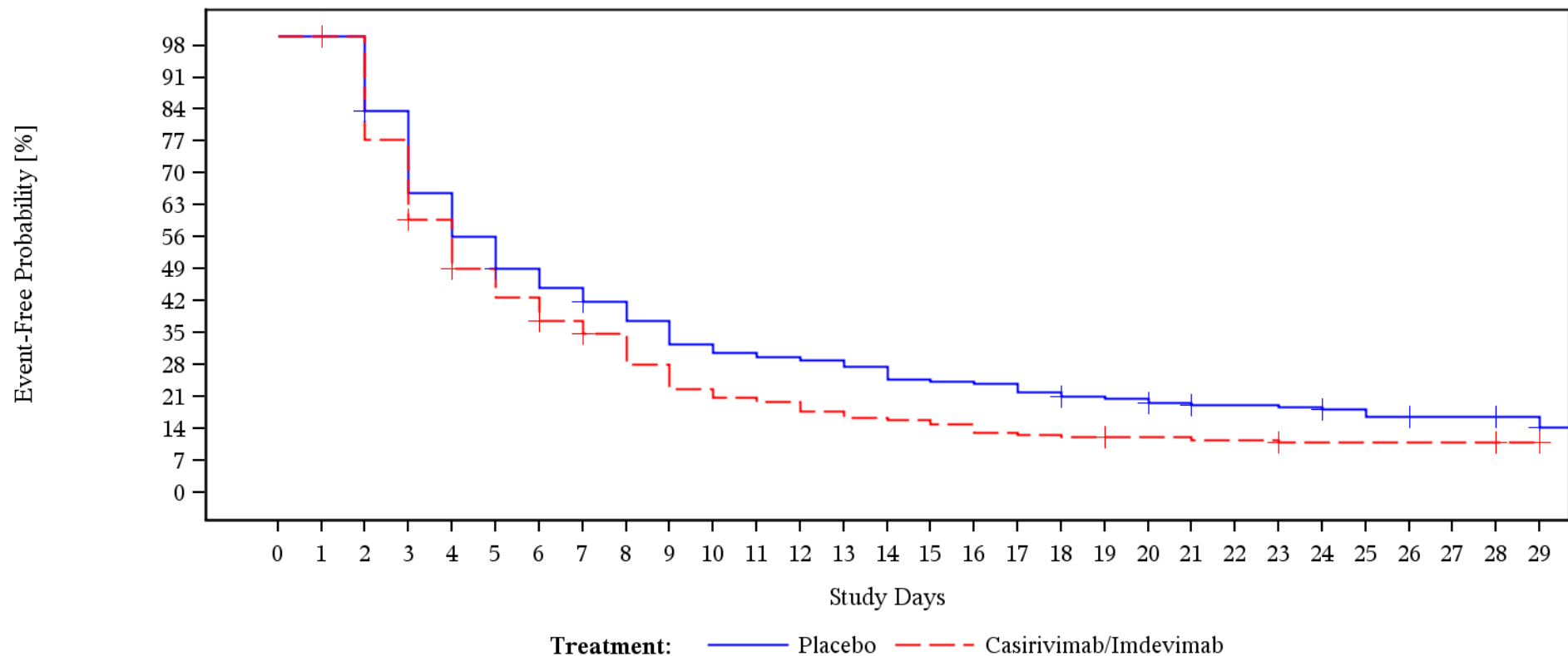
POPULATION: mFAS
 ENDPOINT: Time to first deterioration (MID=10) - Sensitivity Analysis
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	50	6,8	686	93,2	NE	6,00	NE	NE	NE	NE	740	100,0	53	7,1	695	92,9	NE	4,00	NE	NE	NE	NE	0,9083	0,98	0,67	1,44	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-3-eff-tte-ttdets10

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first improvement
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	226	186	146	125	108	99	91	82	71	67	65	63	60	54	53	52	48	45	44	41	39	39	38	36	33	32	32	20
Casirivimab/Imdevimab	736	736	216	167	128	104	91	79	72	58	47	43	41	37	34	33	31	27	26	25	24	24	23	23	21	21	21	21	21	8

Patients Censored

Placebo	0	522	525	525	525	526	526	527	527	527	527	527	527	527	527	527	527	527	528	528	529	530	530	530	531	531	532	532	544	560	
Casirivimab/Imdevimab	0	520	520	521	522	522	523	524	524	524	524	524	524	524	524	524	524	524	524	525	525	525	525	525	526	526	526	526	526	539	547

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-4-km-plot-timp10.pdf

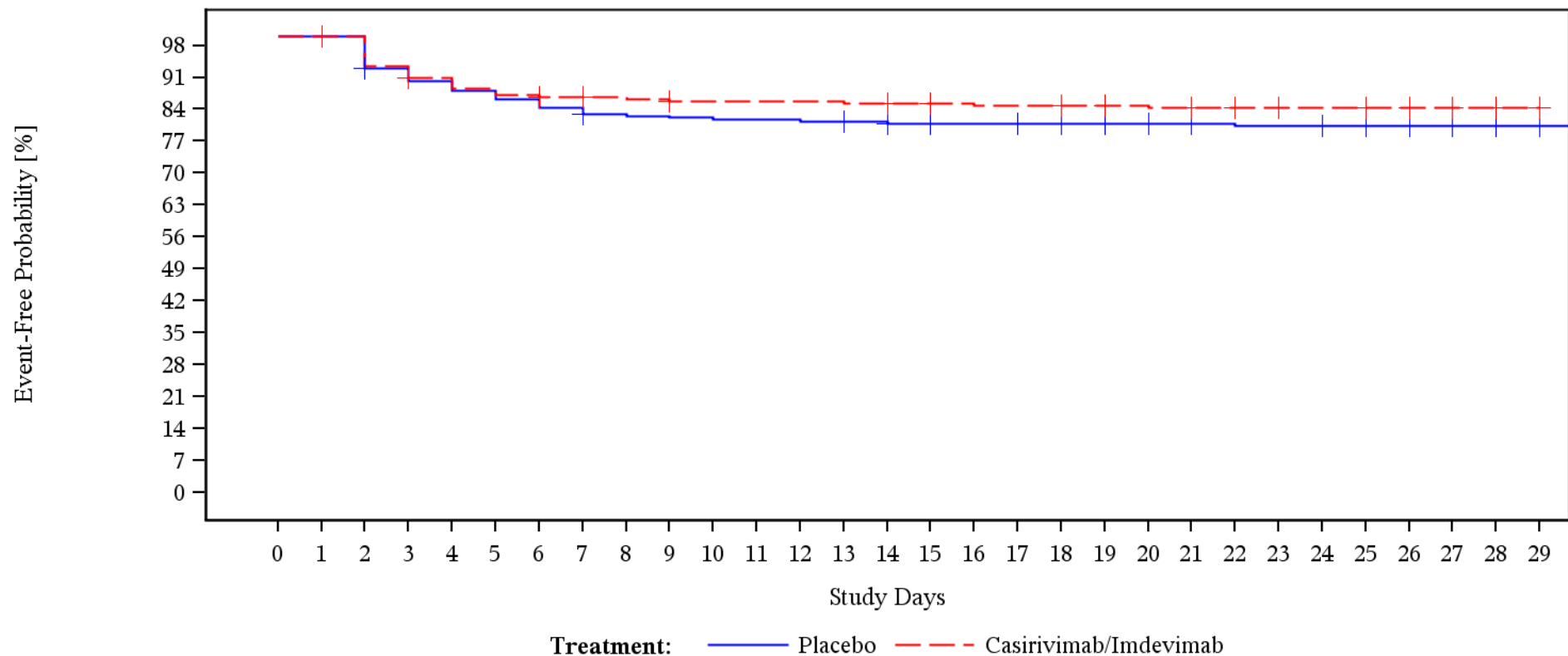
POPULATION: mFAS
 ENDPOINT: Time to first improvement (MID=10)
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	189	25,7	547	74,3	3,00	2,00	3,00	4,00	4,00	5,00	748	100,0	187	25,0	561	75,0	3,00	NE	NE	5,00	4,00	7,00	0,0260	1,24	1,01	1,51	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-4-eff-tte-ttimp10

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	226	207	201	196	192	188	183	182	181	180	180	179	178	175	174	174	173	172	171	168	167	166	166	164	158	150	140	78
Casirivimab/Imdevimab	736	736	217	203	196	191	188	185	184	183	181	181	181	181	180	179	178	177	177	176	174	173	172	171	167	167	165	157	149	79

Patients Censored

Placebo	0	522	525	525	525	525	525	527	527	527	527	527	527	528	530	531	531	532	533	534	537	538	538	538	540	546	554	564	626	703
Casirivimab/Imdevimab	0	519	519	520	520	520	522	523	523	524	524	524	524	525	526	526	526	527	529	529	530	531	535	535	537	545	553	623	702	

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-ttdet15.pdf

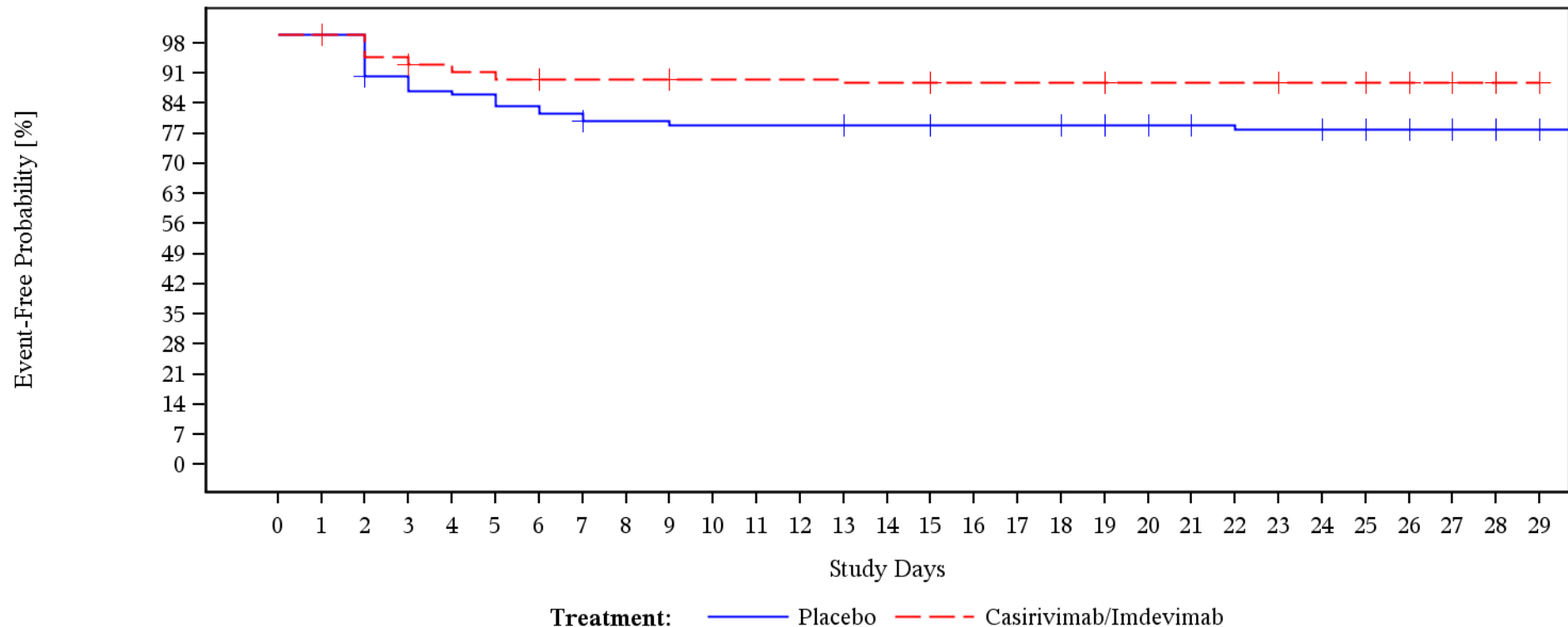
POPULATION: mFAS
 ENDPOINT: Time to first deterioration (MID=15)
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	34	4,6	702	95,4	NE	NE	NE	NE	NE	NE	740	100,0	44	5,9	704	94,1	NE	14,00	NE	NE	NE	NE	0,2974	0,79	0,51	1,24	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-5-eff-tte-ttdet15

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

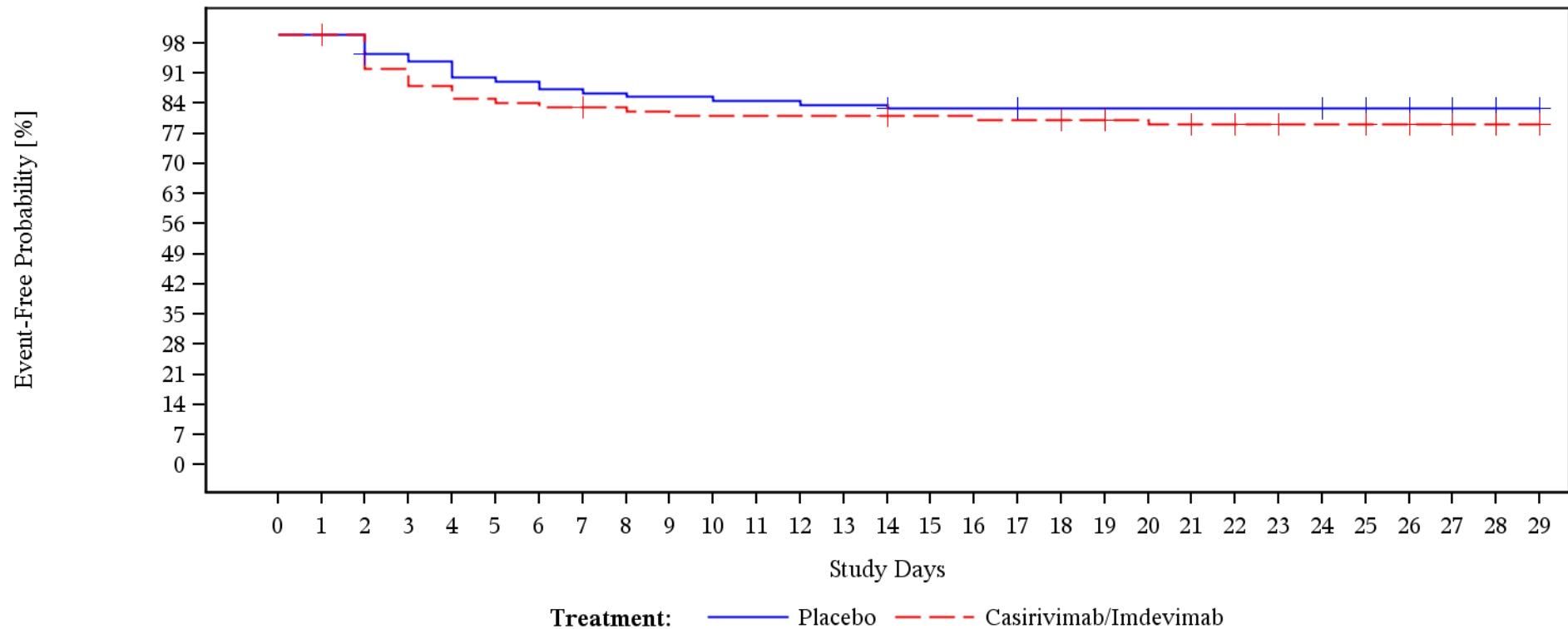
Placebo	352	352	115	102	98	97	94	92	88	88	87	87	87	87	86	86	85	85	85	84	83	80	79	78	78	77	74	70	64	33
Casirivimab/Imdevimab	364	364	116	110	107	105	103	101	101	101	100	100	100	100	99	99	98	98	98	98	97	97	97	97	96	96	95	90	85	46

Patients Censored

Placebo	0	237	239	239	239	239	239	241	241	241	241	241	241	242	242	243	243	243	244	245	248	249	249	249	250	253	257	263	294	326
Casirivimab/Imdevimab	0	248	248	249	249	249	251	251	251	252	252	252	252	252	252	253	253	253	253	254	254	254	254	255	255	256	261	266	305	351

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

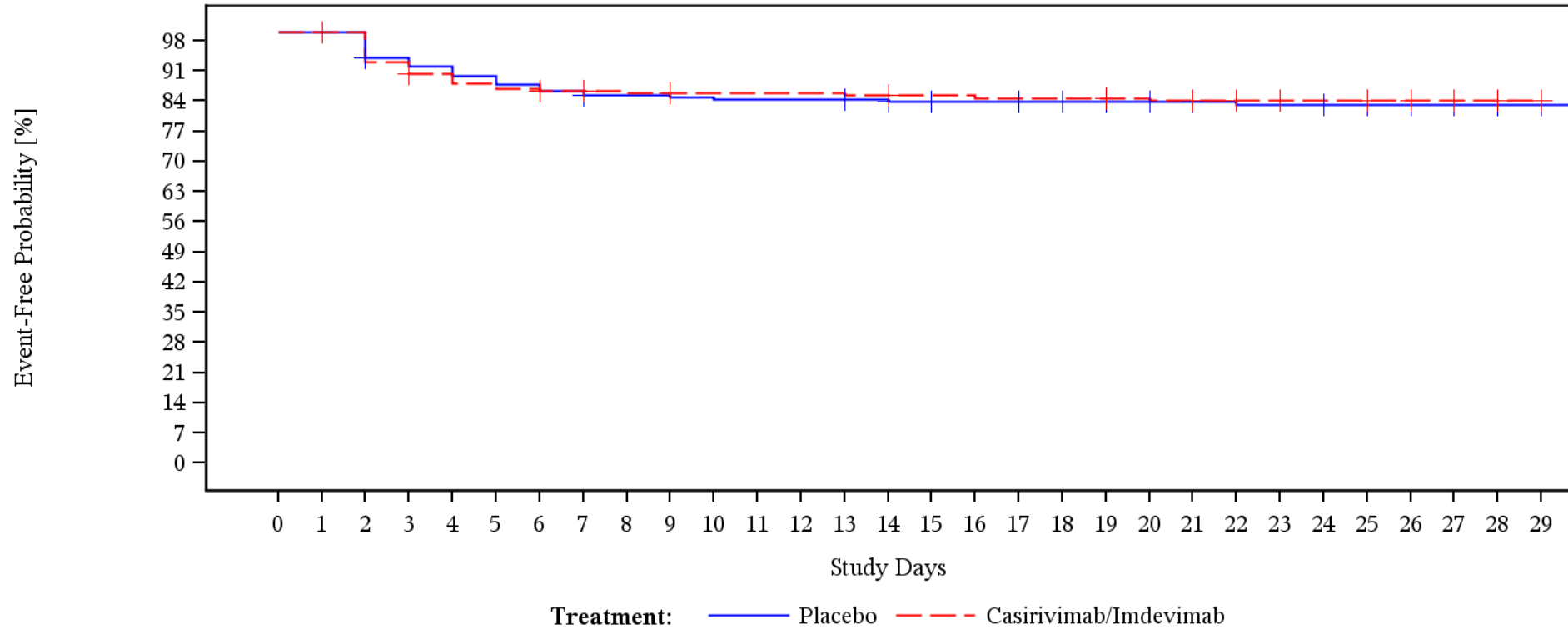
Placebo	396	396	111	105	103	99	98	96	95	94	94	93	93	92	92	89	89	89	88	88	88	88	88	88	87	84	80	76	45
Casirivimab/Imdevimab	372	372	101	93	89	86	85	84	83	82	81	81	81	81	81	80	80	79	79	78	77	76	75	74	71	70	67	64	33

Patients Censored

Placebo	0	285	286	286	286	286	286	286	286	286	286	286	286	286	288	288	288	289	289	289	289	289	289	289	290	293	297	301	332	377
Casirivimab/Imdevimab	0	271	271	271	271	271	271	272	272	272	272	272	272	272	273	273	273	273	274	275	275	276	277	280	280	281	284	287	318	351

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

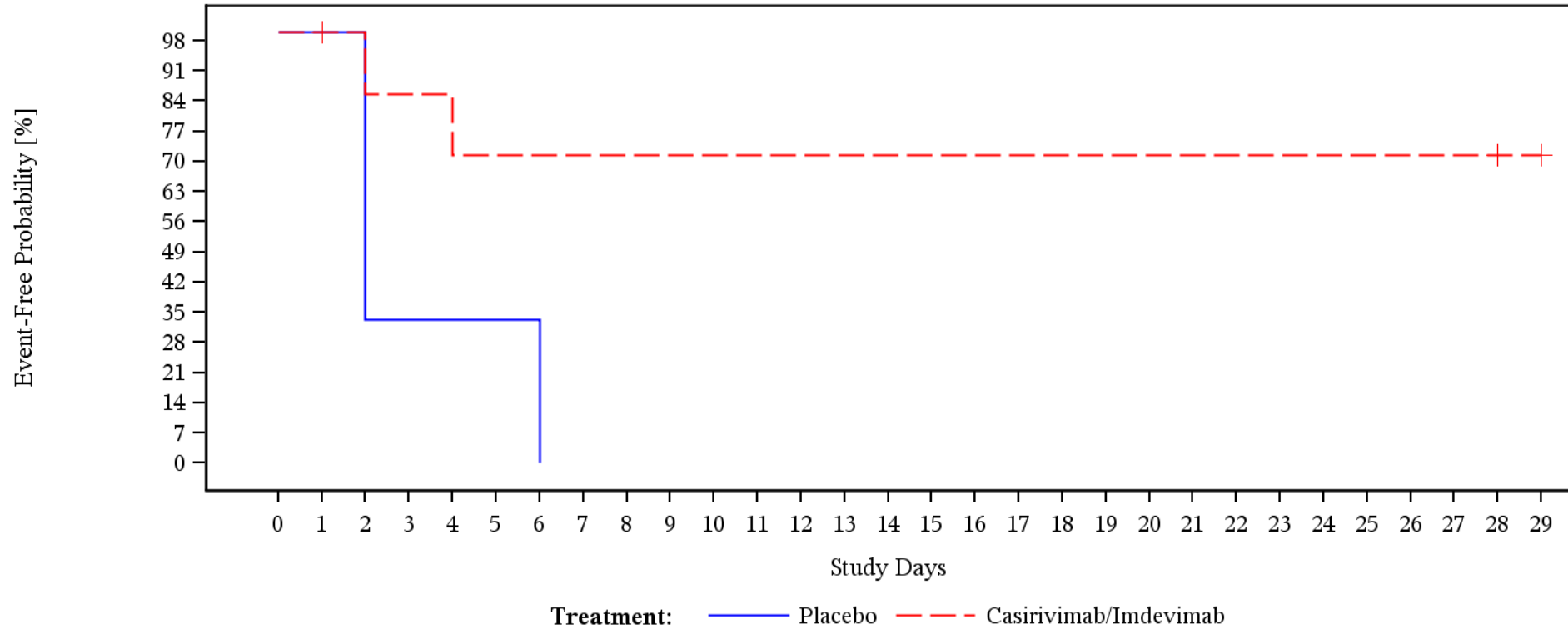
Placebo	660	660	205	191	187	182	178	175	171	171	170	169	169	169	168	166	165	164	163	162	159	158	157	155	149	141	131	72	
Casirivimab/Imdevimab	643	643	184	171	165	161	159	157	156	155	154	154	154	153	152	152	151	151	151	149	148	147	146	143	143	141	133	126	64

Patients Censored

Placebo	0	455	457	457	457	457	457	459	459	459	459	459	459	460	461	462	462	463	464	465	468	469	469	469	471	477	485	495	554	625
Casirivimab/Imdevimab	0	459	459	460	460	460	461	462	462	463	463	463	463	464	464	464	464	464	464	466	466	467	468	471	471	473	481	488	550	614

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

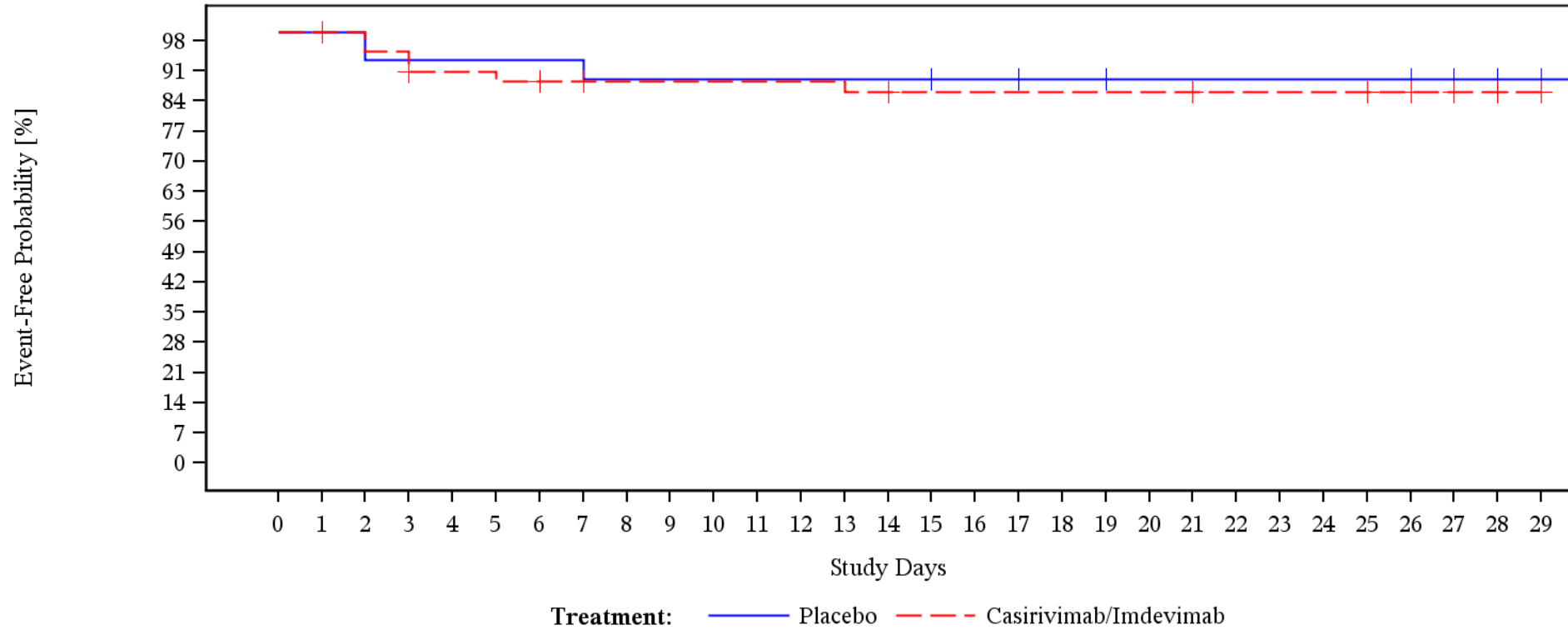
Placebo	20	20	3	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	31	31	7	6	6	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	2

Patients Censored

Placebo	0	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17
Casirivimab/Imdevimab	0	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	27	29

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

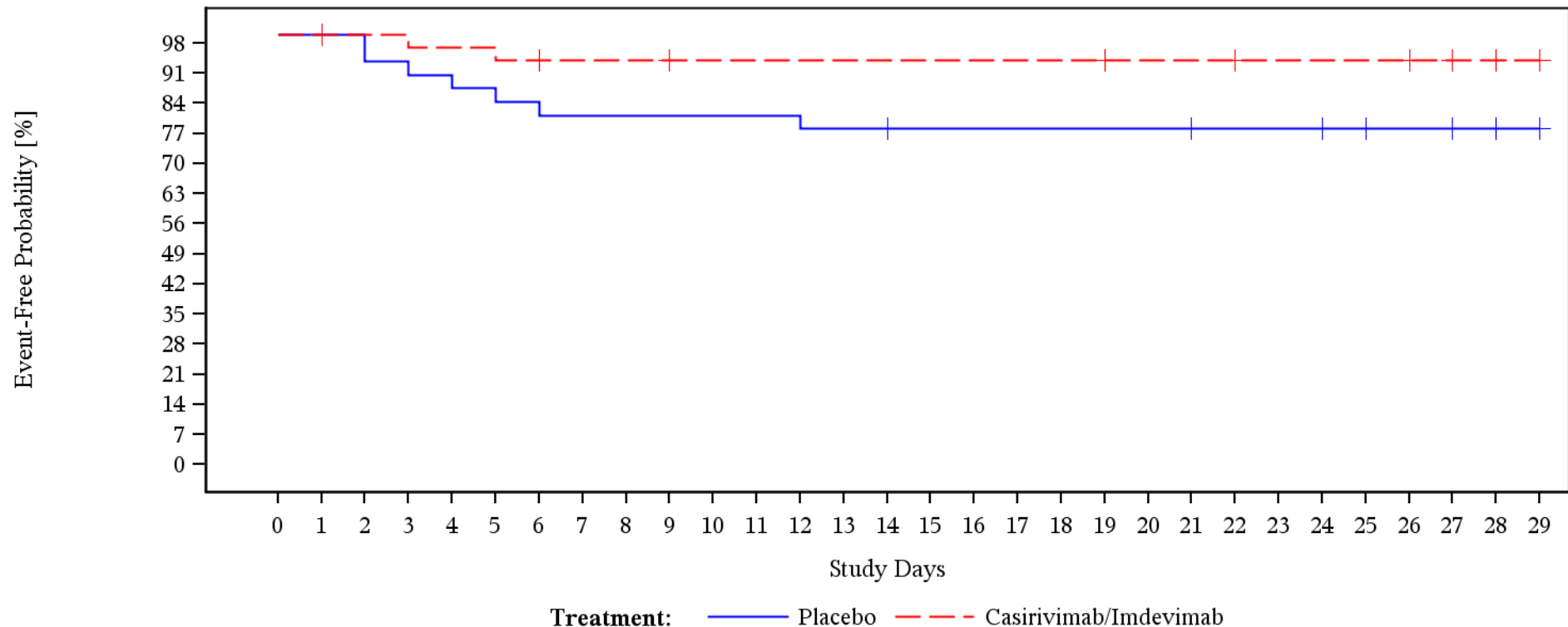
Placebo	150	150	46	43	43	43	43	43	41	41	41	41	41	41	41	40	40	39	39	38	38	38	38	38	38	35	33	23		
Casirivimab/Imdevimab	161	161	44	42	39	39	38	37	36	36	36	36	36	35	34	34	34	34	34	34	34	34	33	33	33	33	32	31	29	12

Patients Censored

Placebo	0	104	104	104	104	104	104	104	104	104	104	104	104	104	105	105	106	106	107	107	107	107	107	107	107	107	110	112	122	144	
Casirivimab/Imdevimab	0	117	117	118	118	118	119	120	120	120	120	120	120	120	121	121	121	121	121	121	121	121	122	122	122	122	123	124	126	143	155

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

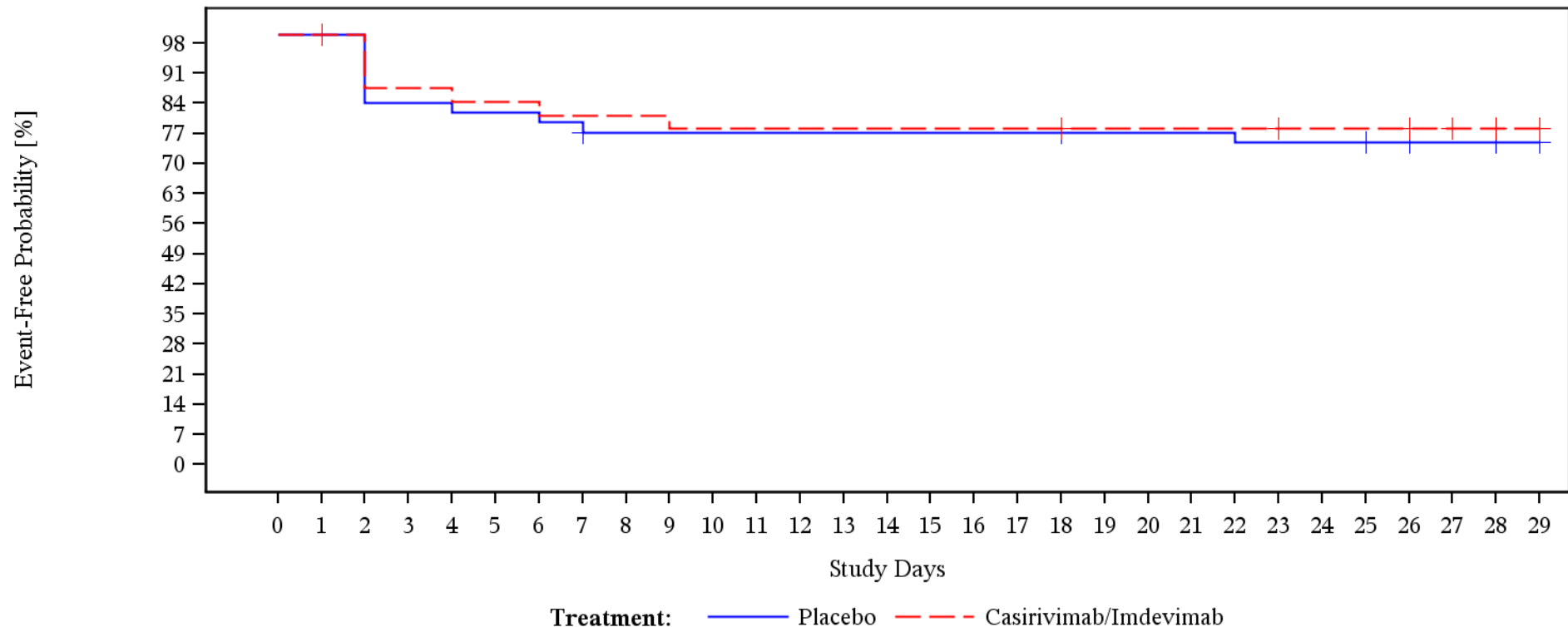
Placebo	123	123	32	30	29	28	27	26	26	26	26	26	25	25	24	24	24	24	24	24	24	23	23	23	22	20	20	19	8
Casirivimab/Imdevimab	91	91	34	34	33	33	32	31	31	31	30	30	30	30	30	30	30	30	29	29	29	28	28	28	28	27	24	15	

Patients Censored

Placebo	0	91	91	91	91	91	91	91	91	91	91	91	91	91	92	92	92	92	92	92	92	93	93	93	94	96	96	97	108	116	
Casirivimab/Imdevimab	0	57	57	57	57	57	58	58	58	59	59	59	59	59	59	59	59	59	59	59	60	60	60	61	61	61	61	62	65	74	89

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

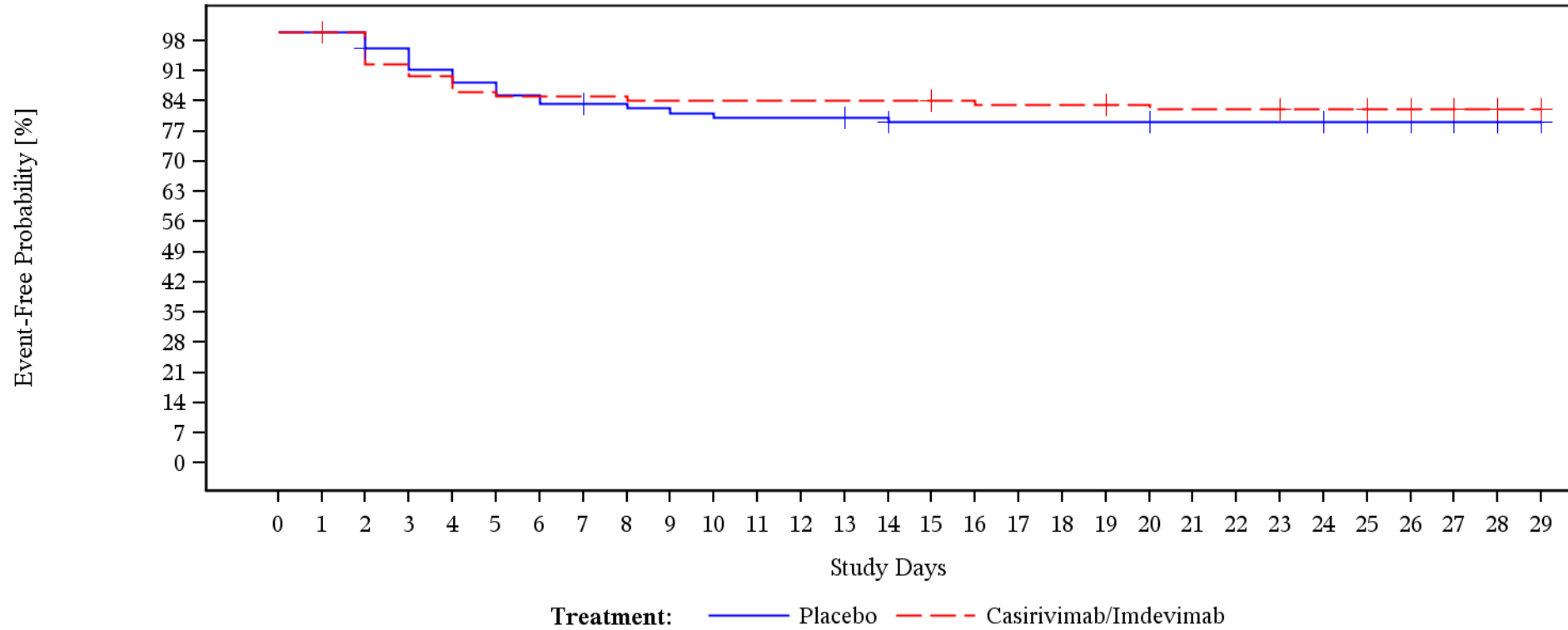
Placebo	125	125	44	37	37	36	36	35	33	33	33	33	33	33	33	33	33	32	32	32	32	31	31	31	29	27	27	16
Casirivimab/Imdevimab	119	119	32	28	28	27	27	26	26	26	25	25	25	25	25	25	25	24	24	24	24	24	23	23	23	22	21	14

Patients Censored

Placebo	0	81	81	81	81	81	81	82	82	82	82	82	82	82	82	82	82	83	83	83	83	83	83	83	85	87	87	98	114	
Casirivimab/Imdevimab	0	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	88	88	88	88	88	88	89	89	89	90	91	98	112

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

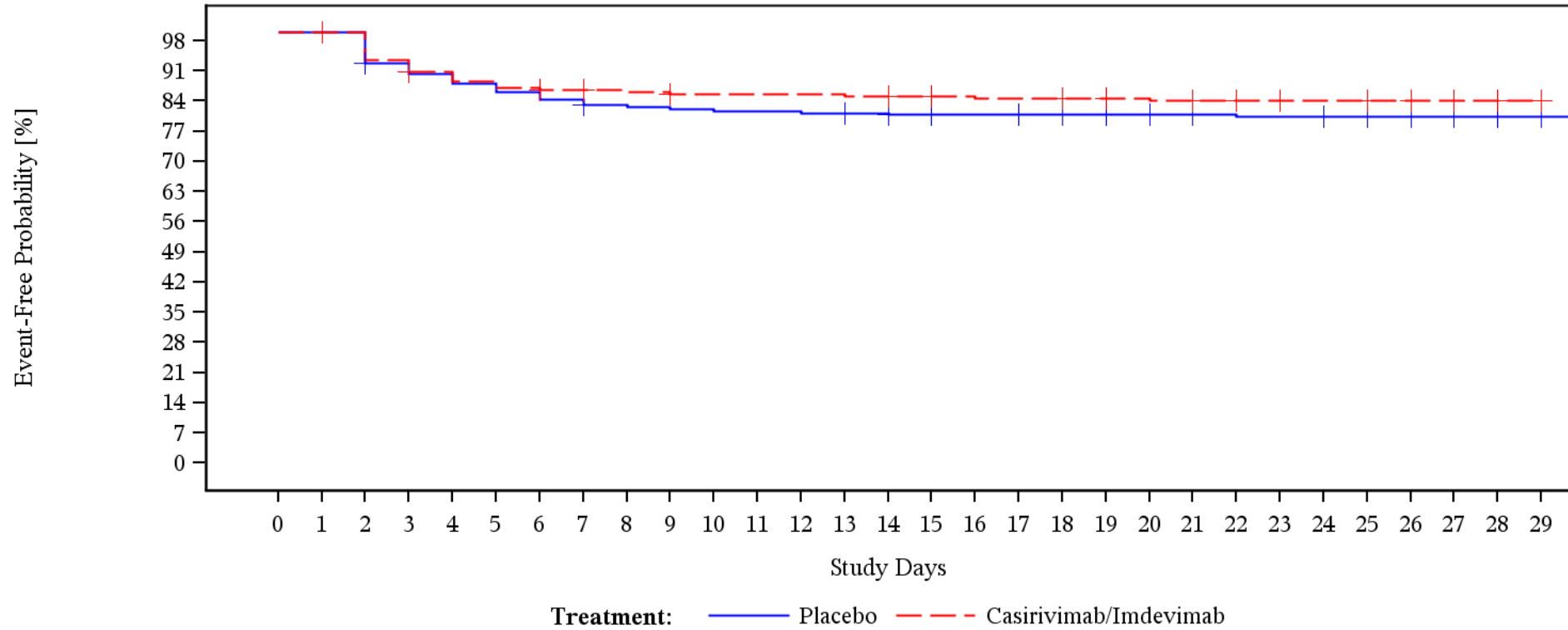
Placebo	346	346	104	97	92	89	86	84	83	82	81	80	80	80	79	77	77	77	77	77	77	74	74	74	74	73	71	68	61	31
Casirivimab/Imdevimab	363	363	107	99	96	92	91	91	91	90	90	90	90	90	90	89	88	88	88	87	86	86	86	83	83	82	77	75	38	

Patients Censored

Placebo	0	242	245	245	245	245	245	246	246	246	246	246	246	247	248	248	248	248	248	248	251	251	251	251	252	254	257	264	294	325
Casirivimab/Imdevimab	0	256	256	256	256	256	256	256	256	256	256	256	256	256	257	257	257	257	258	258	258	258	261	261	262	267	269	306	344	

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

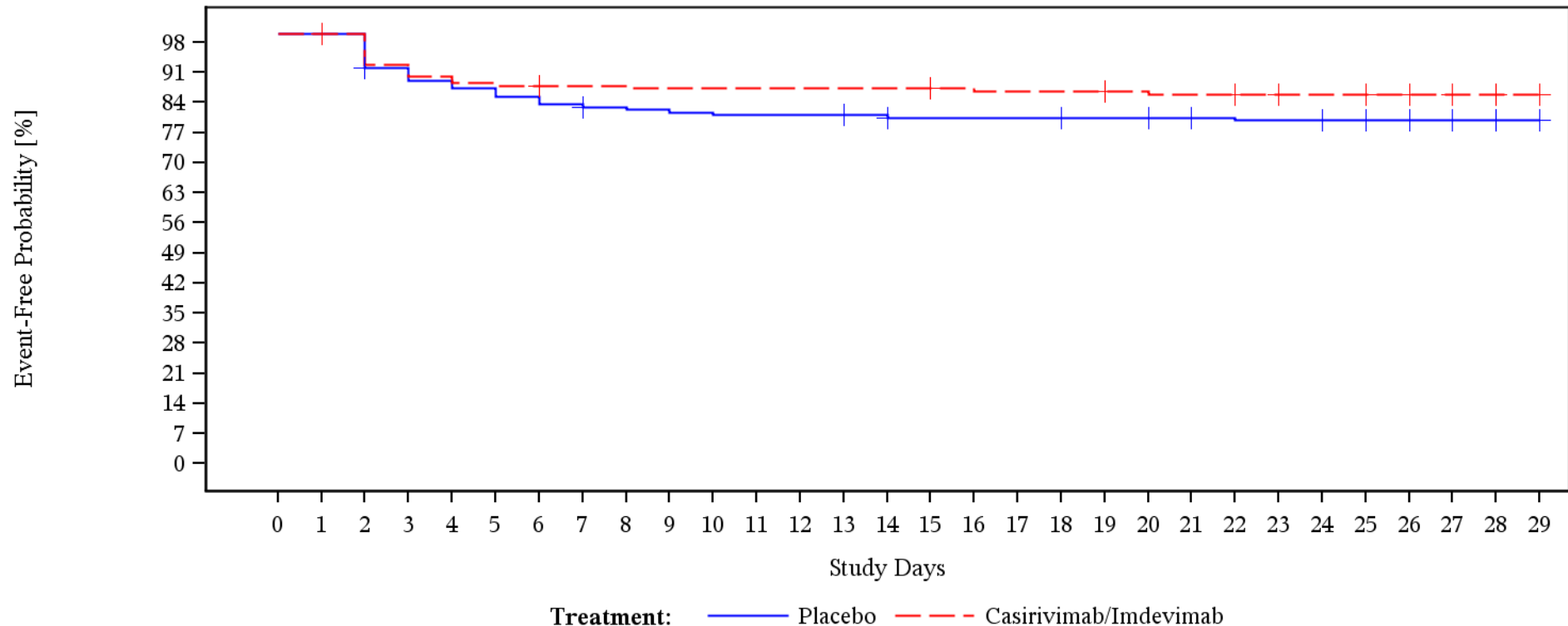
Placebo	711	711	226	207	201	196	192	188	183	182	181	180	180	179	178	175	174	174	173	172	171	168	167	166	166	164	158	150	140	78
Casirivimab/Imdevimab	698	698	217	203	196	191	188	185	184	183	181	181	181	181	180	179	178	177	177	176	174	173	172	171	167	167	165	157	149	79

Patients Censored

Placebo	0	485	488	488	488	488	488	490	490	490	490	490	490	491	493	494	494	495	496	497	500	501	501	501	503	509	517	527	589	666
Casirivimab/Imdevimab	0	481	481	482	482	482	484	485	485	486	486	486	486	487	488	488	488	488	489	491	491	492	493	497	497	499	507	515	585	664

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

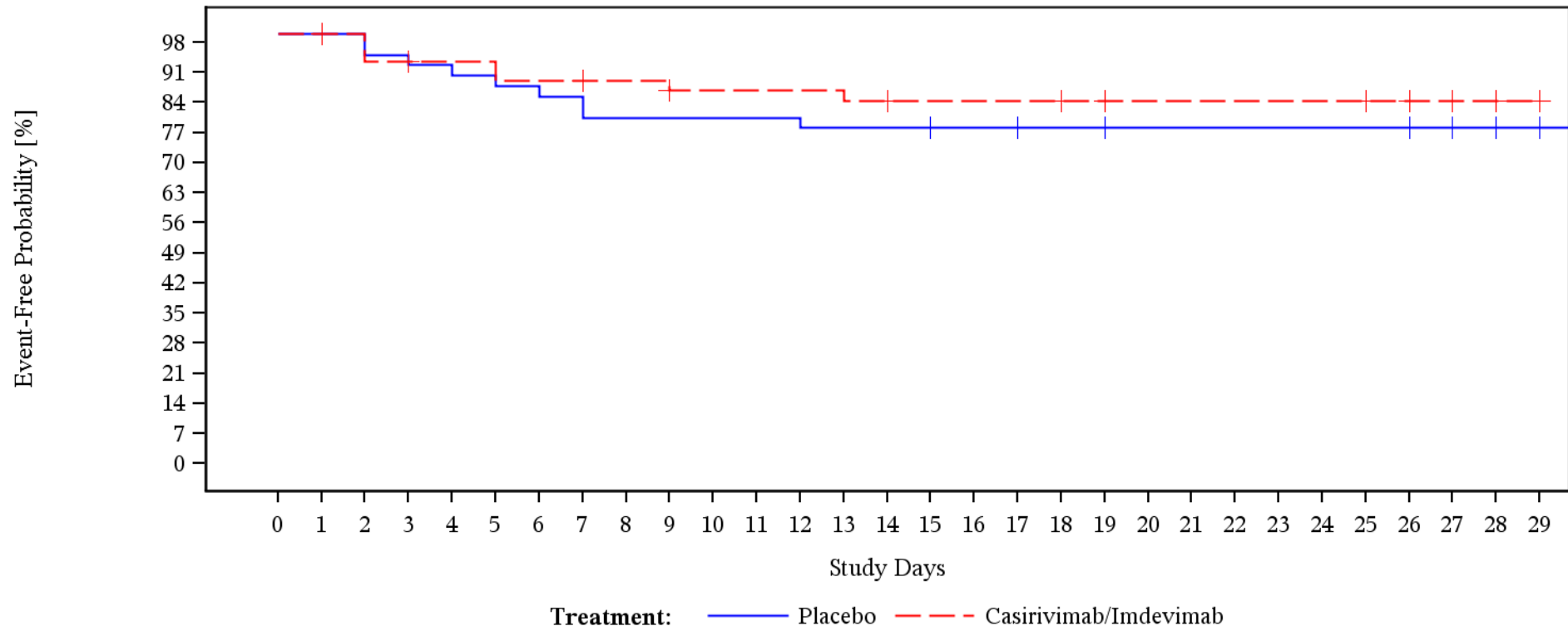
Placebo	519	519	166	150	145	142	139	136	133	132	131	130	130	129	126	126	126	126	125	125	122	121	120	120	118	113	109	100	54
Casirivimab/Imdevimab	500	500	141	131	127	125	124	122	122	121	121	121	121	121	121	120	119	119	119	118	117	117	116	112	112	111	106	103	58

Patients Censored

Placebo	0	353	356	356	356	356	356	358	358	358	358	358	358	359	361	361	361	361	362	362	365	366	366	366	368	373	377	386	432	486
Casirivimab/Imdevimab	0	359	359	359	359	359	361	361	361	361	361	361	361	361	361	362	362	362	362	363	363	363	364	368	368	369	374	377	422	480

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

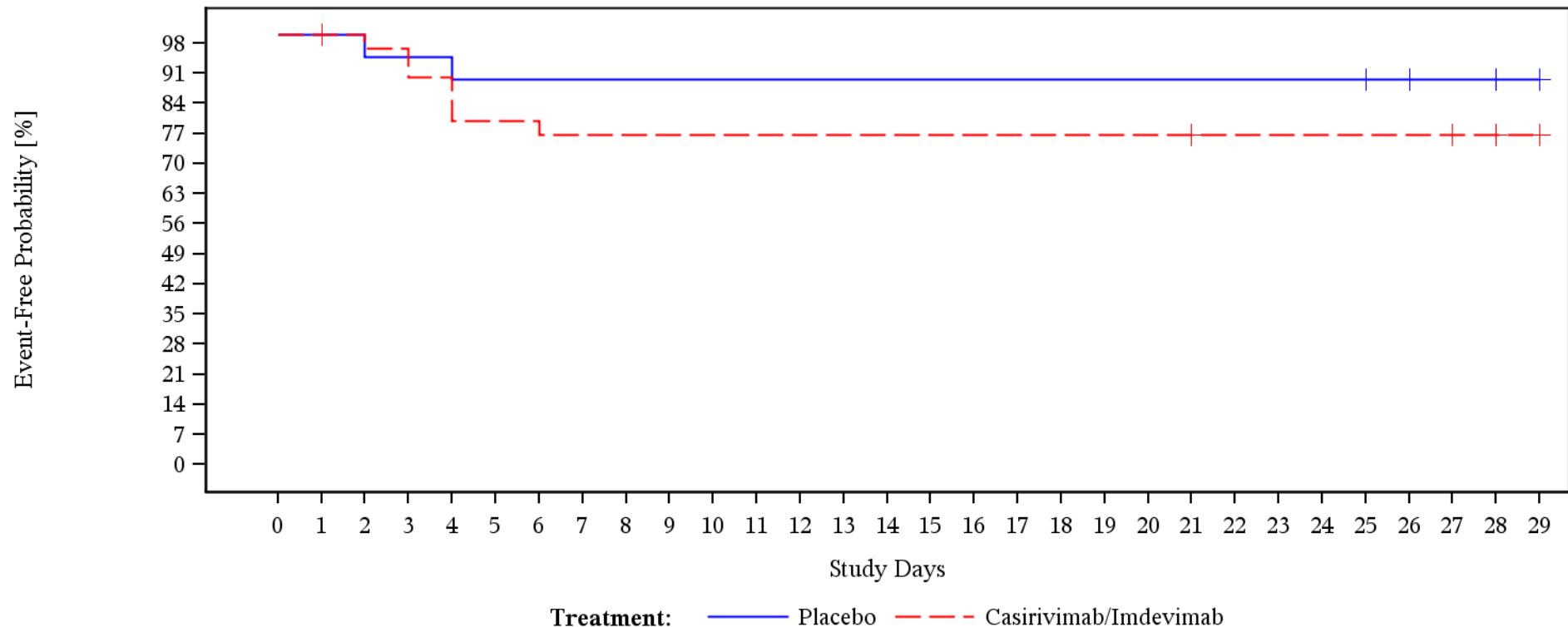
Placebo	164	164	41	39	38	37	36	35	33	33	33	33	32	32	31	31	30	30	29	29	29	29	29	29	26	25	19	
Casirivimab/Imdevimab	177	177	46	43	42	42	40	40	39	39	37	37	37	36	35	35	35	35	34	33	33	33	33	33	32	29	25	10

Patients Censored

Placebo	0	123	123	123	123	123	123	123	123	123	123	123	123	123	124	124	125	125	126	126	126	126	126	126	126	129	130	136	154		
Casirivimab/Imdevimab	0	131	131	132	132	132	132	133	133	134	134	134	134	134	135	135	135	135	136	137	137	137	137	137	137	137	138	141	145	160	170

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	65	65	19	18	18	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	16	15	15	5	
Casirivimab/Imdevimab	59	59	30	29	27	24	24	23	23	23	23	23	23	23	23	23	23	23	23	22	22	22	22	22	22	21	11

Patients Censored

Placebo	0	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	47	48	48	58	63	
Casirivimab/Imdevimab	0	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	30	30	30	30	30	30	31	41	52

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

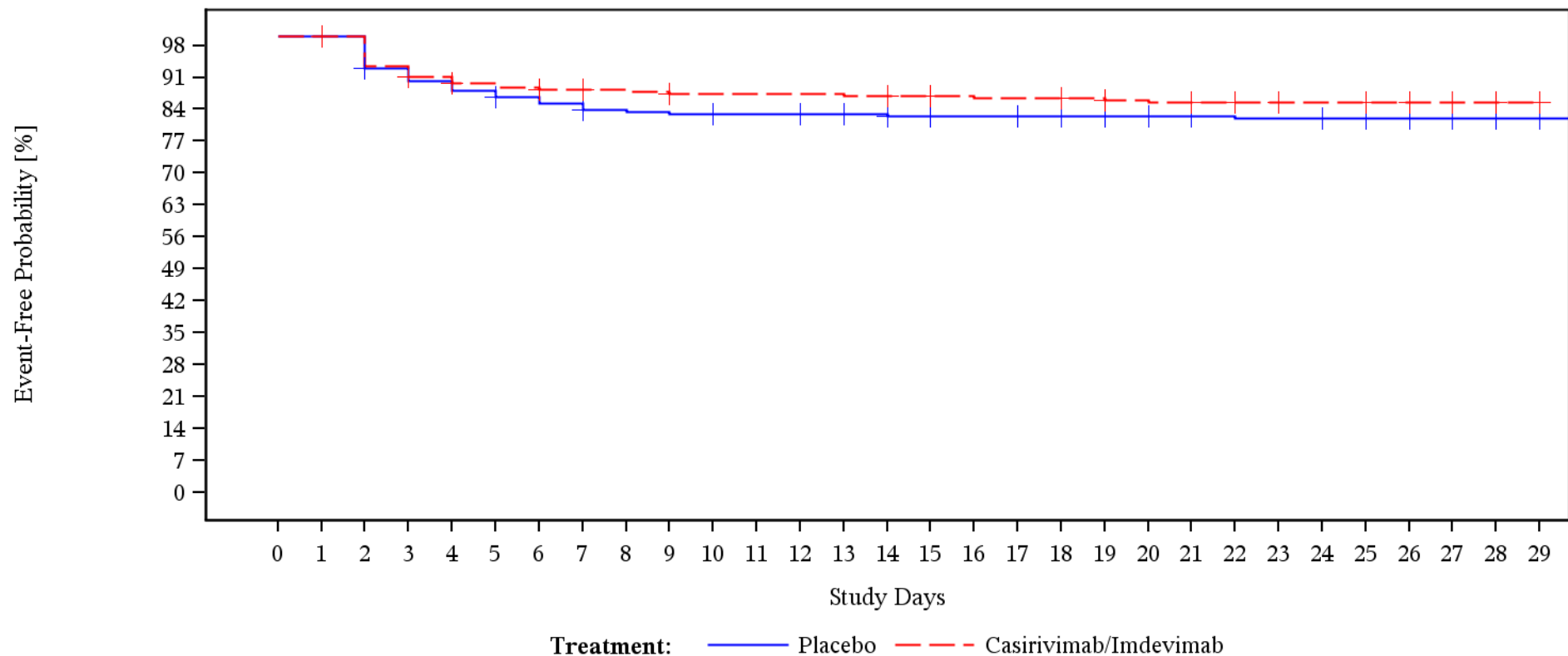
POPULATION: mFAS
 ENDPOINT: Time to first deterioration (MID=15)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo						Casirivimab/Imdevimab vs. Placebo					Interaction Test								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank p-value	Hazard Ratio			p-value (likelihood ratio)			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median			95% Upper CL for Median	Hazard Ratio	95% Lower CL		95% Upper CL	Convergence Status	
All	n/a	736	100,0	34	4,6	702	95,4	NE	NE	NE	NE	NE	NE	740	100,0	44	5,9	704	94,1	NE	14,00	NE	NE	NE	NE	0,2974	0,79	0,51	1,24	Convergence criterion (GCONV=1E-8) satisfied.			
Sex	Male	364	49,5	13	3,6	351	96,4	NE	NE	NE	NE	NE	NE	352	47,1	25	7,1	327	92,9	NE	6,00	NE	NE	NE	NE	0,0306	0,49	0,25	0,96	Convergence criterion (GCONV=1E-8) satisfied.	0,0443		
	Female	372	50,5	21	5,6	351	94,4	NE	6,00	NE	NE	NE	NE	396	52,9	19	4,8	377	95,2	NE	14,00	NE	NE	NE	NE	0,4756	1,25	0,67	2,32	Convergence criterion (GCONV=1E-8) satisfied.			
Age	18-64	643	87,4	29	4,5	614	95,5	NE	NE	NE	NE	NE	NE	660	88,2	34	5,2	626	94,8	NE	NE	NE	NE	NE	NE	0,8441	0,95	0,58	1,56	Convergence criterion (GCONV=1E-8) satisfied.	0,0466		
	65-74	62	8,4	3	4,8	59	95,2	NE	5,00	NE	NE	NE	NE	68	9,1	7	10,3	61	89,7	7,00	2,00	NE	NE	3,00	NE	0,0244	0,24	0,06	0,94	Convergence criterion (GCONV=1E-8) satisfied.			
	>=75	31	4,2	2	6,5	29	93,5	4,00	2,00	NE	NE	2,00	NE	20	2,7	3	15,0	17	85,0	2,00	2,00	6,00	2,00	6,00	0,0389	0,20	0,03	1,25	Convergence criterion (GCONV=1E-8) satisfied.				
Baseline viral load categories	<=10^5 copies/mL	161	21,9	6	3,7	155	96,3	NE	5,00	NE	NE	NE	NE	150	20,1	5	3,3	145	96,7	NE	NE	NE	NE	NE	NE	0,6691	1,29	0,39	4,23	Convergence criterion (GCONV=1E-8) satisfied.	0,4333		
	>10^5 copies/mL - <=10^6 copies/mL	91	12,4	2	2,2	89	97,8	NE	NE	NE	NE	NE	NE	123	16,4	7	5,7	116	94,3	NE	3,00	NE	NE	NE	NE	0,0614	0,25	0,05	1,21	Convergence criterion (GCONV=1E-8) satisfied.			
	>10^6 copies/mL - <=10^7 copies/mL	119	16,2	7	5,9	112	94,1	NE	2,00	NE	NE	NE	NE	125	16,7	11	8,8	114	91,2	22,00	2,00	NE	NE	NE	NE	0,7475	0,86	0,33	2,22	Convergence criterion (GCONV=1E-8) satisfied.			
	>10^7 copies/mL	363	49,3	19	5,2	344	94,8	NE	16,00	NE	NE	NE	NE	346	46,3	21	6,1	325	93,9	NE	6,00	NE	NE	NE	NE	0,6397	0,86	0,47	1,61	Convergence criterion (GCONV=1E-8) satisfied.			
	Unknown	2	0,3	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	4	0,5	0	0,0	4	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Country	USA	698	94,8	34	4,9	664	95,1	NE	NE	NE	NE	NE	NE	711	95,1	44	6,2	667	93,8	NE	14,00	NE	NE	NE	NE	NE	0,2974	0,79	0,51	1,24	Convergence criterion (GCONV=1E-8) satisfied.		
	MEX	38	5,2	0	0,0	38	100,0	NE	NE	NE	NE	NE	NE	37	4,9	0	0,0	37	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Baseline serostatus	Negative	500	67,9	20	4,0	480	96,0	NE	NE	NE	NE	NE	NE	519	69,4	33	6,4	486	93,6	NE	9,00	NE	NE	NE	NE	NE	0,1851	0,69	0,40	1,21	Convergence criterion (GCONV=1E-8) satisfied.	0,3522	
	Positive	177	24,0	7	4,0	170	96,0	NE	9,00	NE	NE	NE	NE	164	21,9	9	5,5	155	94,5	NE	5,00	NE	NE	NE	NE	NE	0,4514	0,69	0,26	1,85	Convergence criterion (GCONV=1E-8) satisfied.		
	Other	59	8,0	7	11,9	52	88,1	NE	3,00	NE	NE	NE	NE	65	8,7	2	3,1	63	96,9	NE	2,00	NE	NE	NE	NE	NE	0,2788	2,29	0,48	11,01	Convergence criterion (GCONV=1E-8) satisfied.		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-5-eff-tte-ttdet15

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration - Sensitivity Analysis
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	226	207	201	196	191	188	183	182	181	180	180	179	178	175	174	174	173	172	171	168	167	166	166	164	158	150	140	78
Casirivimab/Imdevimab	736	736	216	202	195	191	189	186	185	184	182	182	182	182	181	180	179	178	178	177	174	173	172	171	167	167	165	157	149	79

Patients Censored

Placebo	0	522	525	525	525	527	527	529	529	529	530	530	531	532	534	535	535	536	537	538	541	542	542	542	544	550	558	568	630	707
Casirivimab/Imdevimab	0	520	520	522	523	523	525	526	526	527	527	527	527	527	528	529	529	529	530	532	532	533	534	538	538	540	548	556	626	705

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-6-km-plot-ttdets15.pdf

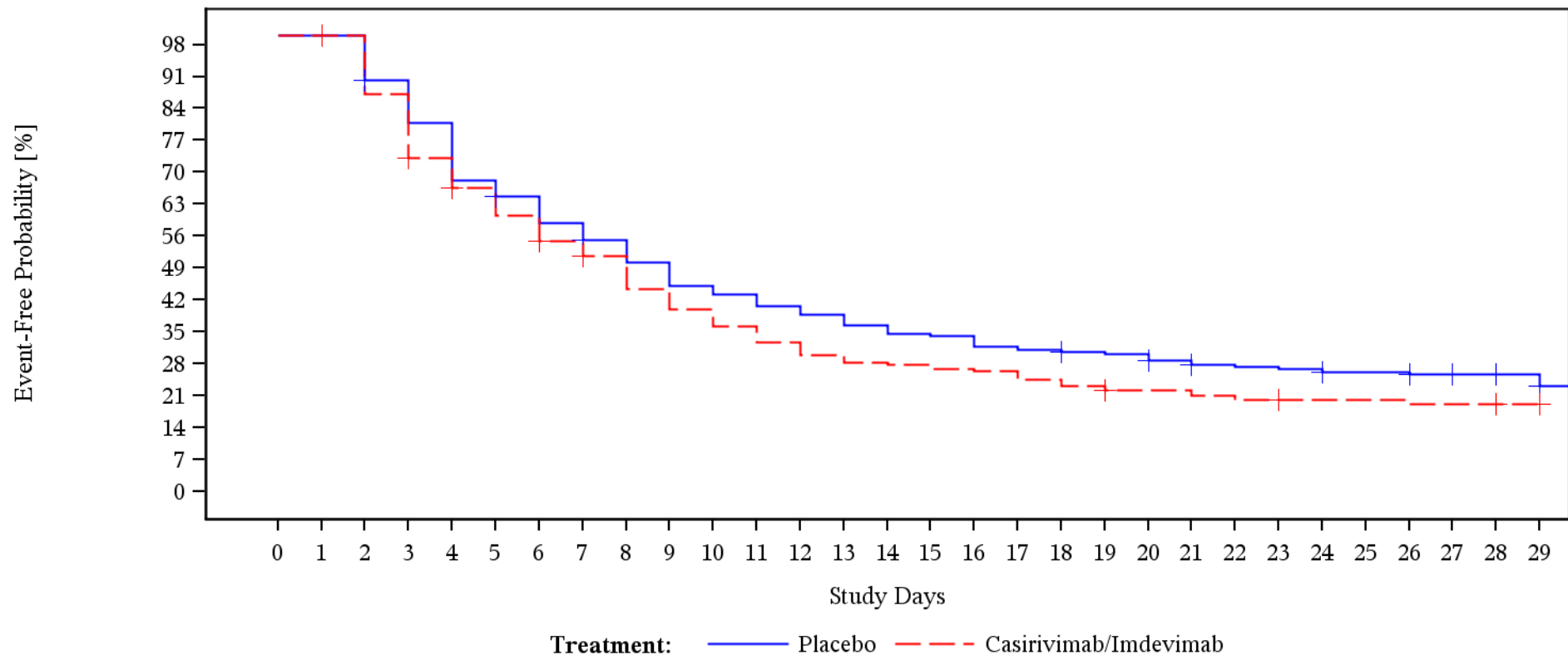
POPULATION: mFAS
 ENDPOINT: Time to first deterioration (MID=15) - Sensitivity Analysis
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	31	4,2	705	95,8	NE	NE	NE	NE	NE	NE	740	100,0	40	5,3	708	94,7	NE	NE	NE	NE	NE	NE	0,3304	0,80	0,50	1,27	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-6-eff-tte-ttdets15

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	226	201	180	152	143	130	121	110	99	95	89	85	80	76	75	70	68	66	65	61	58	57	56	54	54	51	49	28
Casirivimab/Imdevimab	736	736	216	188	157	142	129	115	107	92	83	75	68	62	59	58	56	55	51	48	45	45	43	41	39	39	39	37	37	18

Patients Censored

Placebo	0	522	525	525	525	526	526	527	527	527	527	527	527	527	527	527	527	527	528	528	529	530	530	530	531	531	533	535	556	580	
Casirivimab/Imdevimab	0	520	520	521	522	522	524	525	525	525	525	525	525	525	525	525	525	525	525	526	526	526	526	526	528	528	528	528	528	547	565

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-timp15.pdf

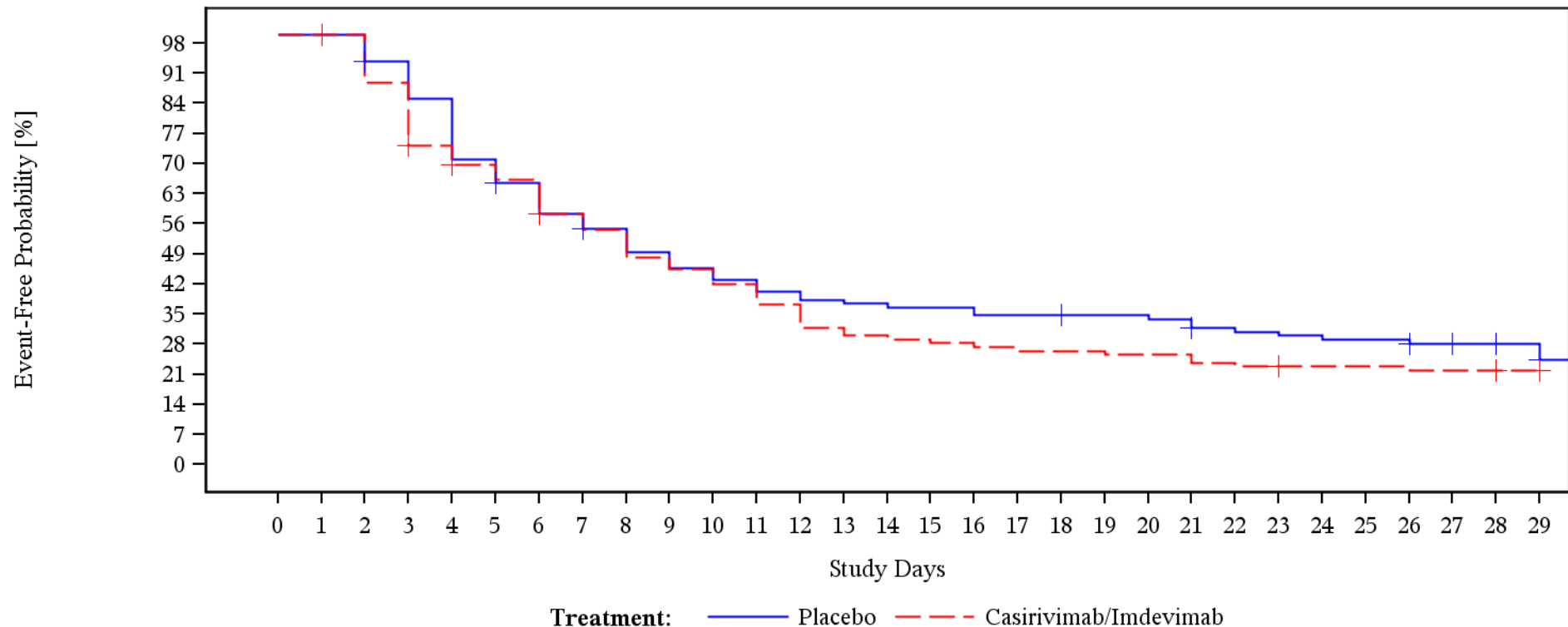
POPULATION: mFAS
 ENDPOINT: Time to first improvement (MID=15)
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	171	23,2	565	76,8	3,00	3,00	4,00	8,00	6,00	9,00	748	100,0	167	22,3	581	77,7	4,00	NE	NE	9,00	7,00	10,00	0,1086	1,18	0,95	1,46	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-7-eff-tte-ttimp15

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

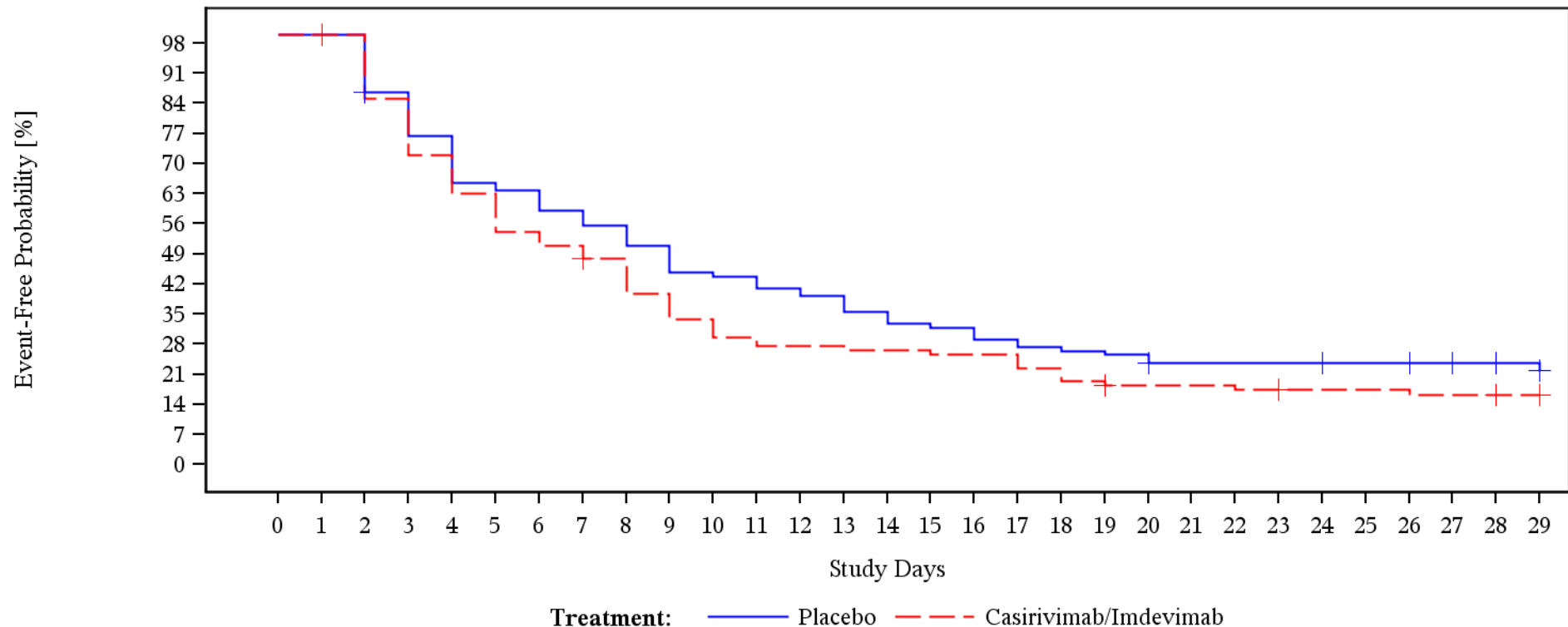
Placebo	352	352	115	106	96	80	73	65	60	54	50	47	44	42	41	40	40	38	38	37	37	36	33	32	31	30	30	28	27	15
Casirivimab/Imdevimab	364	364	116	103	85	79	75	64	60	53	50	46	41	35	33	32	31	30	29	29	28	28	26	25	24	24	24	23	23	10

Patients Censored

Placebo	0	237	239	239	239	240	240	241	241	241	241	241	241	241	241	241	241	241	242	242	242	243	243	243	243	243	244	245	257	269
Casirivimab/Imdevimab	0	248	248	249	250	250	252	252	252	252	252	252	252	252	252	252	252	252	252	252	252	252	252	253	253	253	253	253	266	276

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

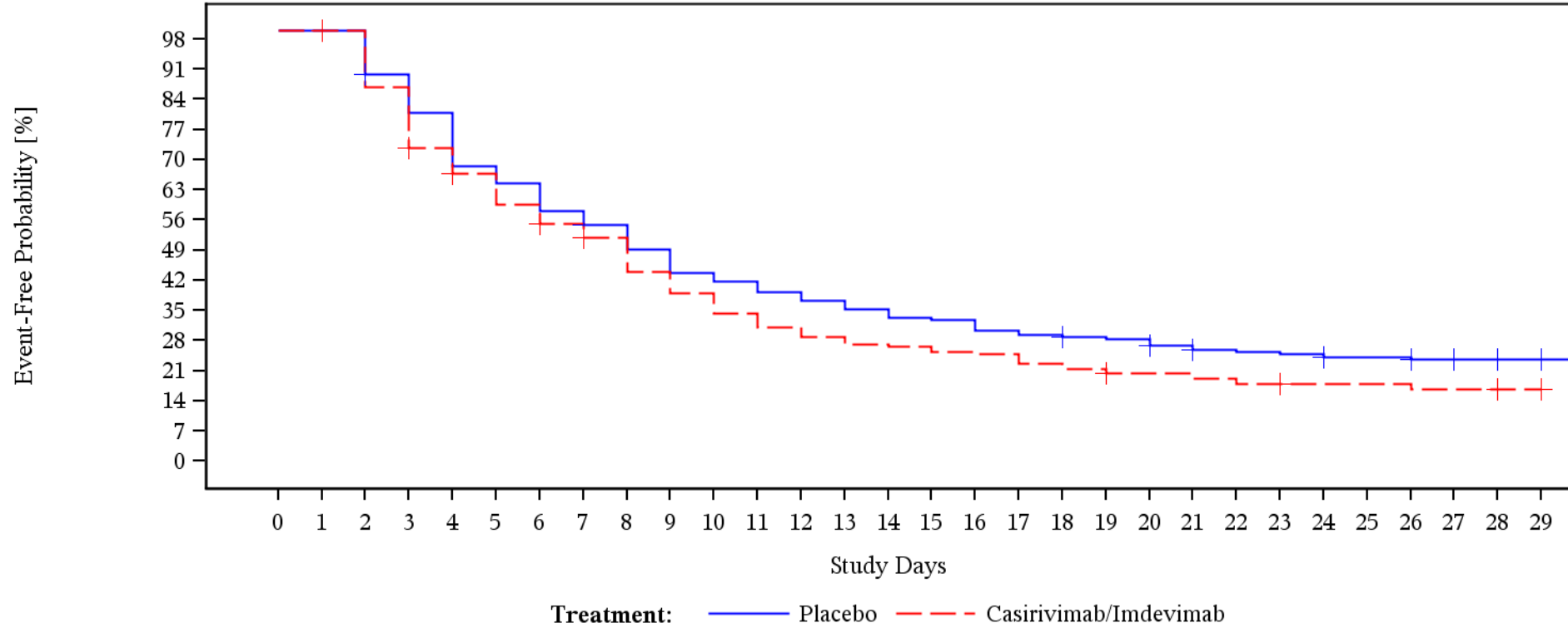
Placebo	396	396	111	95	84	72	70	65	61	56	49	48	45	43	39	36	35	32	30	29	28	25	25	25	25	24	24	23	22	13
Casirivimab/Imdevimab	372	372	100	85	72	63	54	51	47	39	33	29	27	27	26	26	25	25	22	19	17	17	17	16	15	15	15	14	14	8

Patients Censored

Placebo	0	285	286	286	286	286	286	286	286	286	286	286	286	286	286	286	286	286	286	286	287	287	287	287	288	288	289	290	299	311
Casirivimab/Imdevimab	0	272	272	272	272	272	272	273	273	273	273	273	273	273	273	273	273	273	273	274	274	274	274	275	275	275	275	275	281	289

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

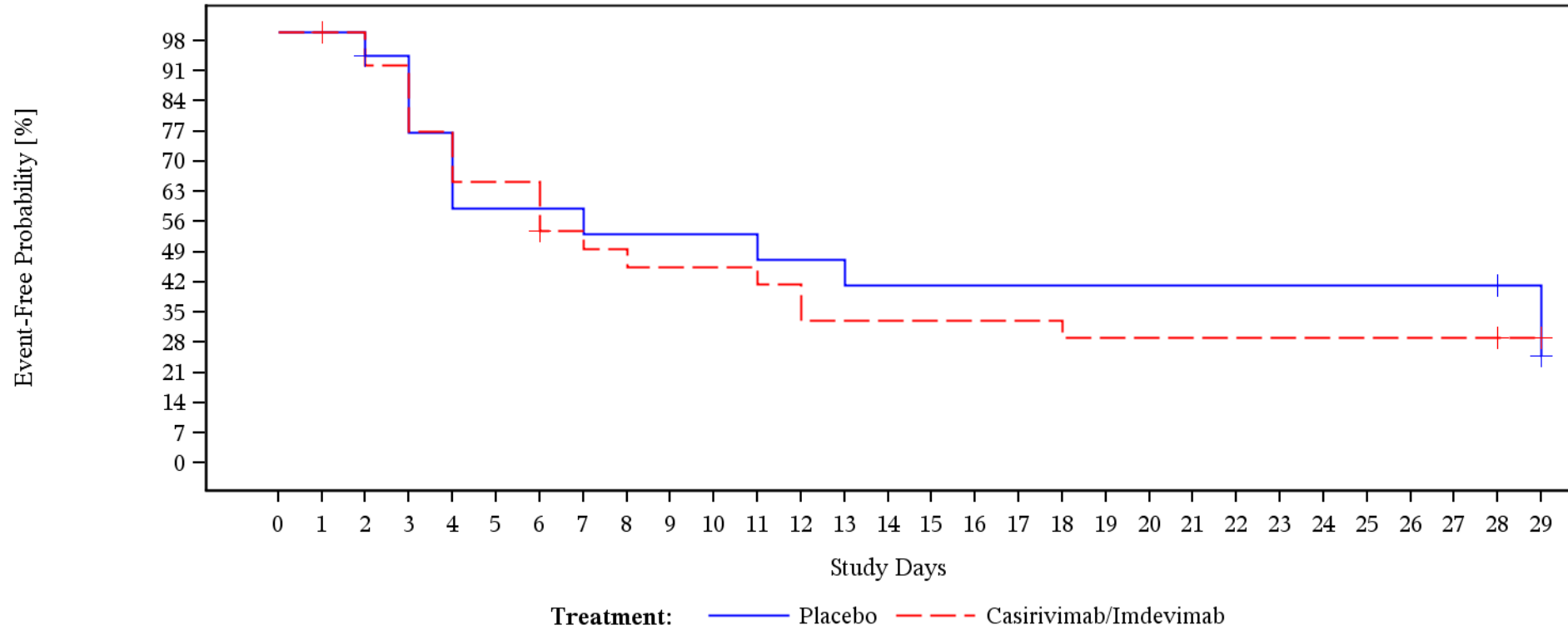
Placebo	660	660	205	182	164	139	131	118	110	99	88	84	79	75	71	67	66	61	59	57	56	52	49	48	47	45	45	42	40	22
Casirivimab/Imdevimab	643	643	184	160	133	121	108	99	92	78	69	61	55	51	48	47	45	44	40	38	35	35	33	31	29	29	29	27	27	14

Patients Censored

Placebo	0	455	457	457	457	457	458	458	458	458	458	458	458	458	458	458	458	459	459	460	461	461	461	462	462	464	466	484	505	
Casirivimab/Imdevimab	0	459	459	460	461	461	462	463	463	463	463	463	463	463	463	463	463	463	464	464	464	464	466	466	466	466	466	466	479	493

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

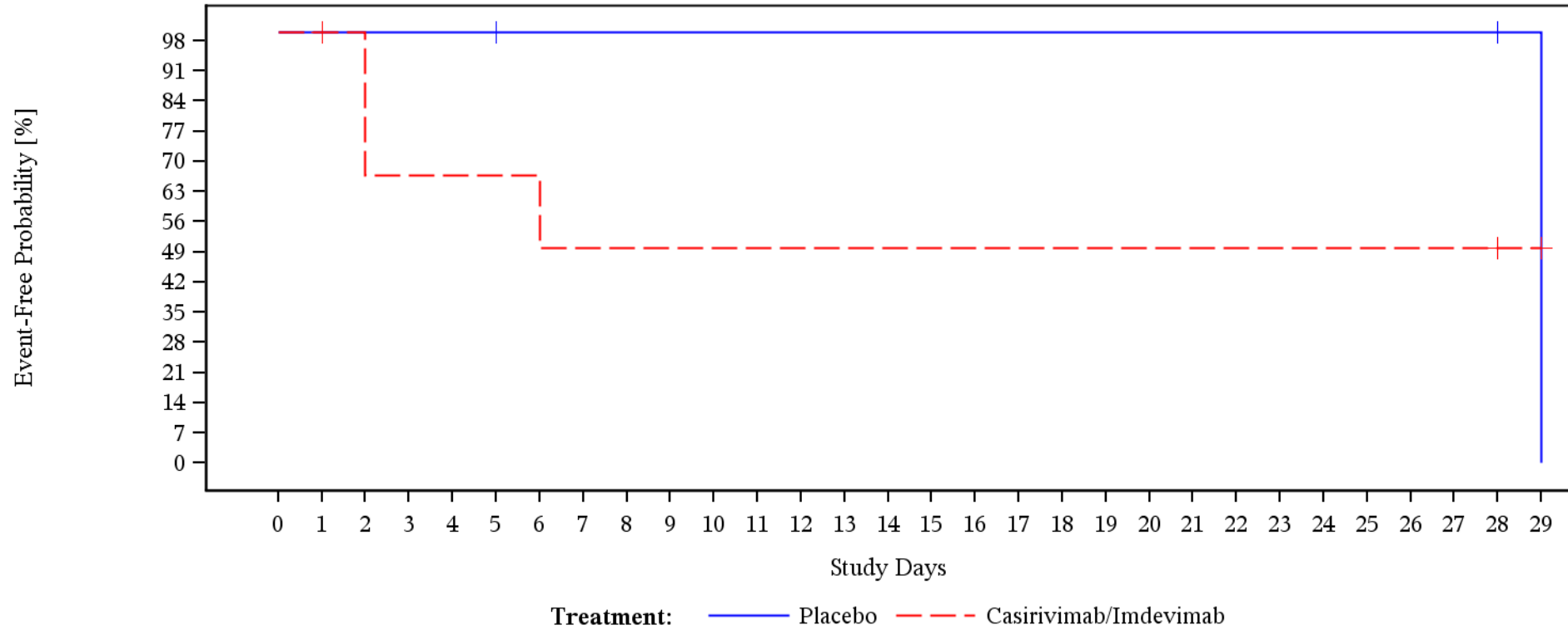
Placebo	68	68	18	16	13	10	10	10	9	9	9	9	8	8	7	7	7	7	7	7	7	7	7	7	7	7	5
Casirivimab/Imdevimab	62	62	26	24	20	17	17	13	12	11	11	11	10	8	8	8	8	8	8	7	7	7	7	7	7	7	2

Patients Censored

Placebo	0	50	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	53	56	
Casirivimab/Imdevimab	0	36	36	36	36	36	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	42	44

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

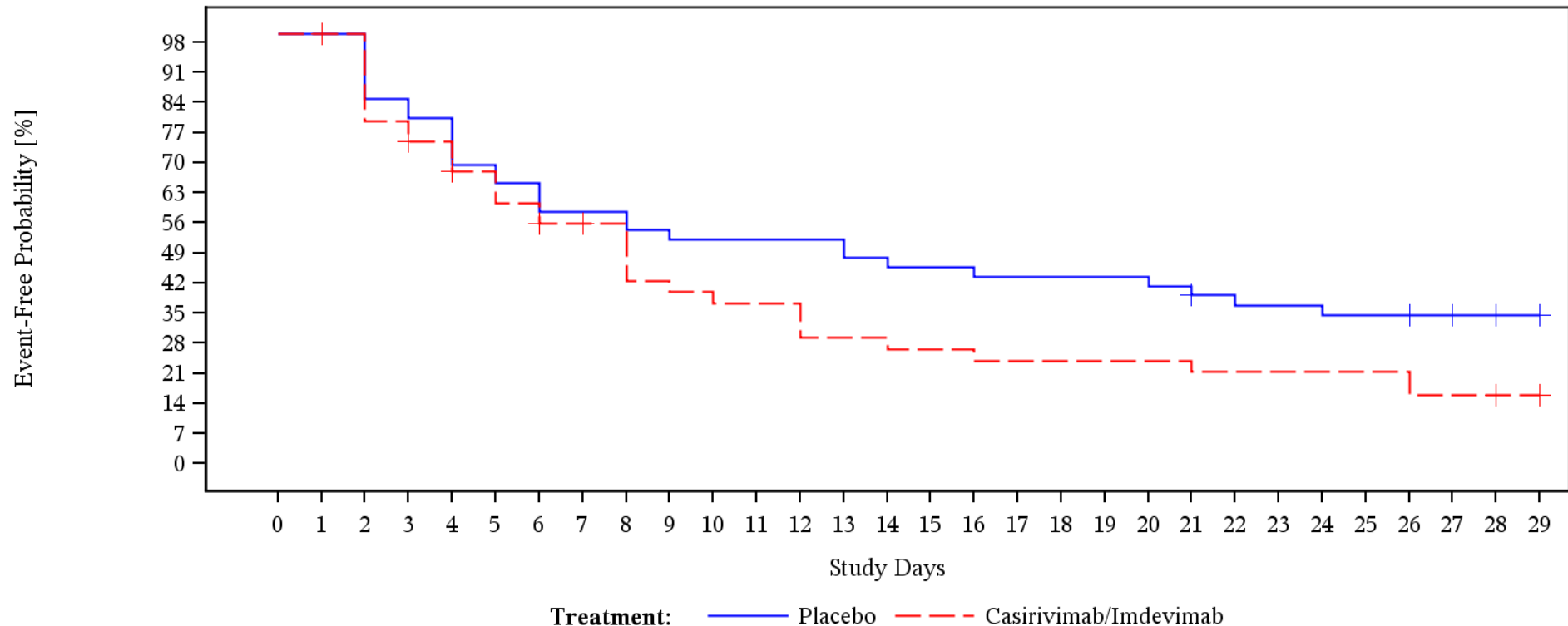
Placebo	20	20	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
Casirivimab/Imdevimab	31	31	6	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2

Patients Censored

Placebo	0	17	17	17	17	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	19	19
Casirivimab/Imdevimab	0	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	26	28

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

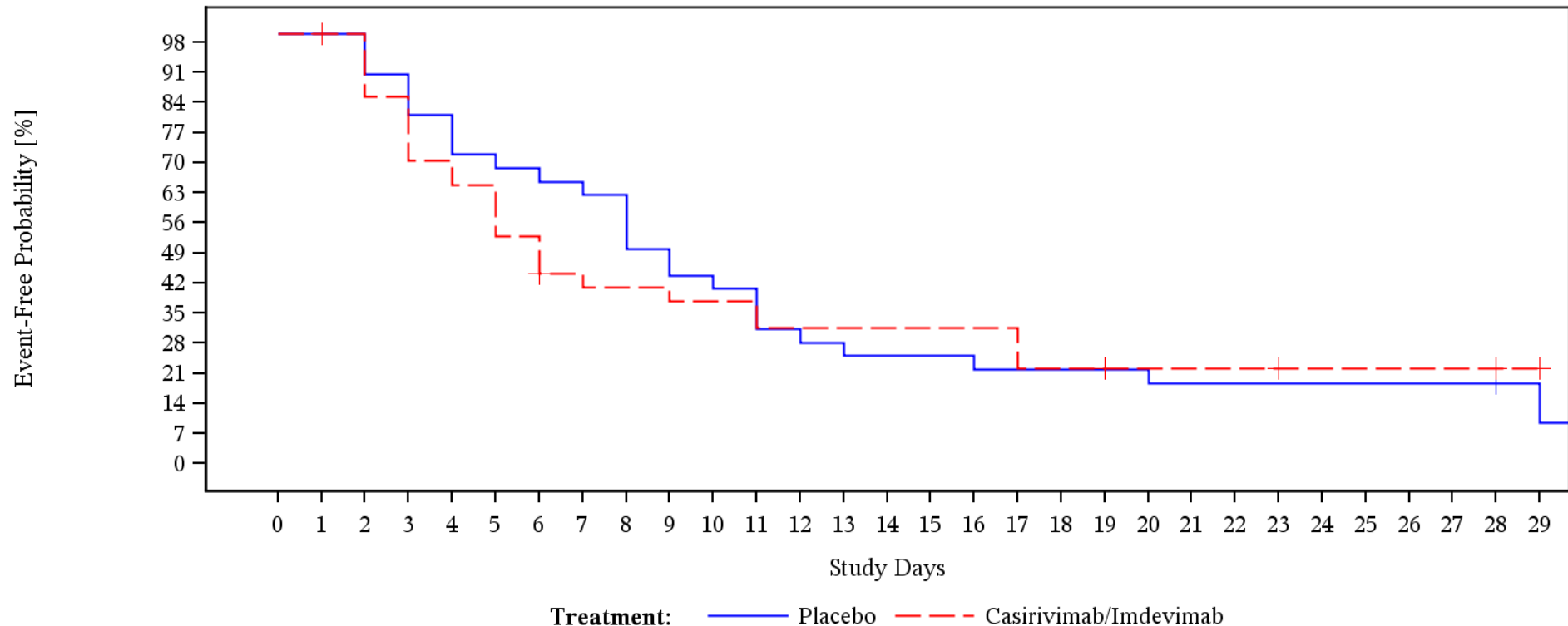
Placebo	150	150	46	39	37	32	30	27	27	25	24	24	24	24	22	21	21	20	20	20	20	19	17	16	16	15	15	13	12	9
Casirivimab/Imdevimab	161	161	44	35	32	28	25	22	21	16	15	14	14	11	11	10	10	9	9	9	9	9	8	8	8	8	8	6	6	3

Patients Censored

Placebo	0	104	104	104	104	104	104	104	104	104	104	104	104	104	104	104	104	104	104	104	104	105	105	105	105	105	107	108	111	120
Casirivimab/Imdevimab	0	117	117	118	119	119	120	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	121	124	127

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

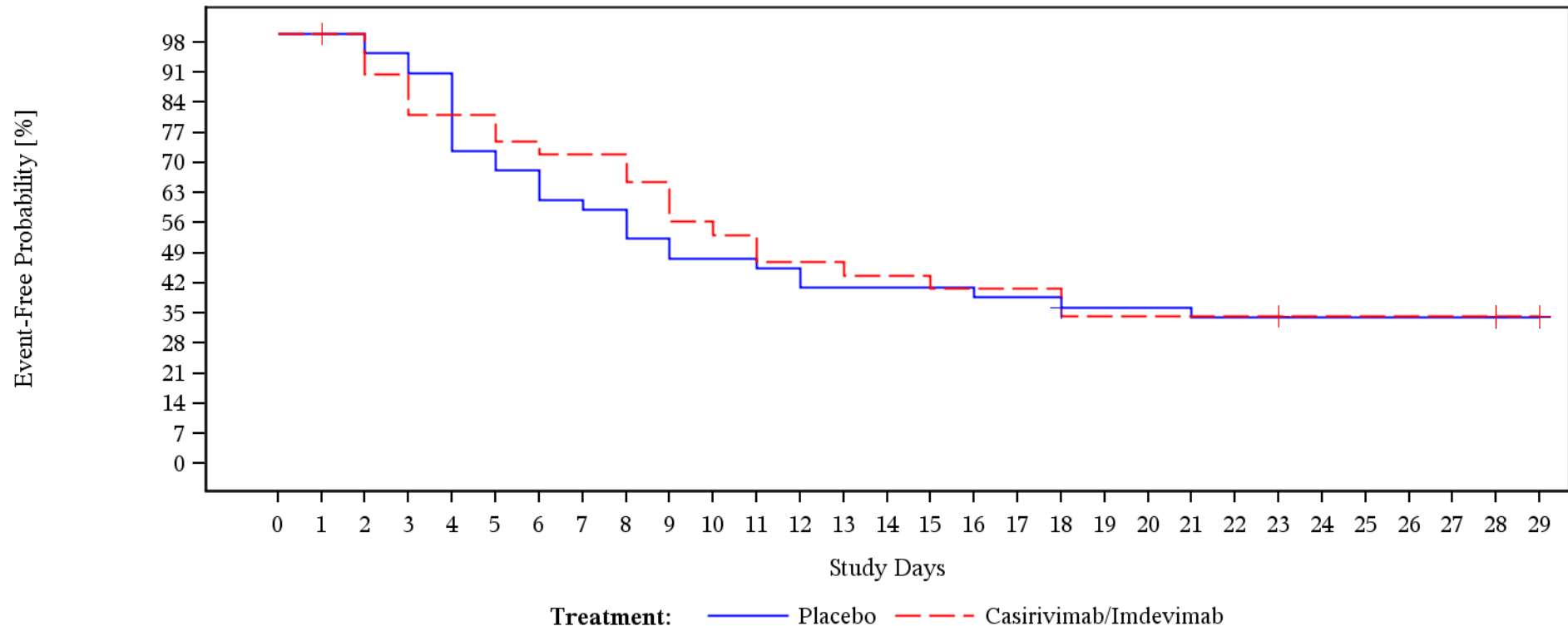
Placebo	123	123	32	29	26	23	22	21	20	16	14	13	10	9	8	8	8	7	7	7	7	6	6	6	6	6	6	6	6	2
Casirivimab/Imdevimab	91	91	34	29	24	22	18	14	13	13	12	12	10	10	10	10	10	10	7	7	6	6	6	6	5	5	5	5	5	2

Patients Censored

Placebo	0	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	95	95	
Casirivimab/Imdevimab	0	57	57	57	57	57	58	58	58	58	58	58	58	58	58	58	58	58	58	59	59	59	59	59	60	60	60	60	60	63	65

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

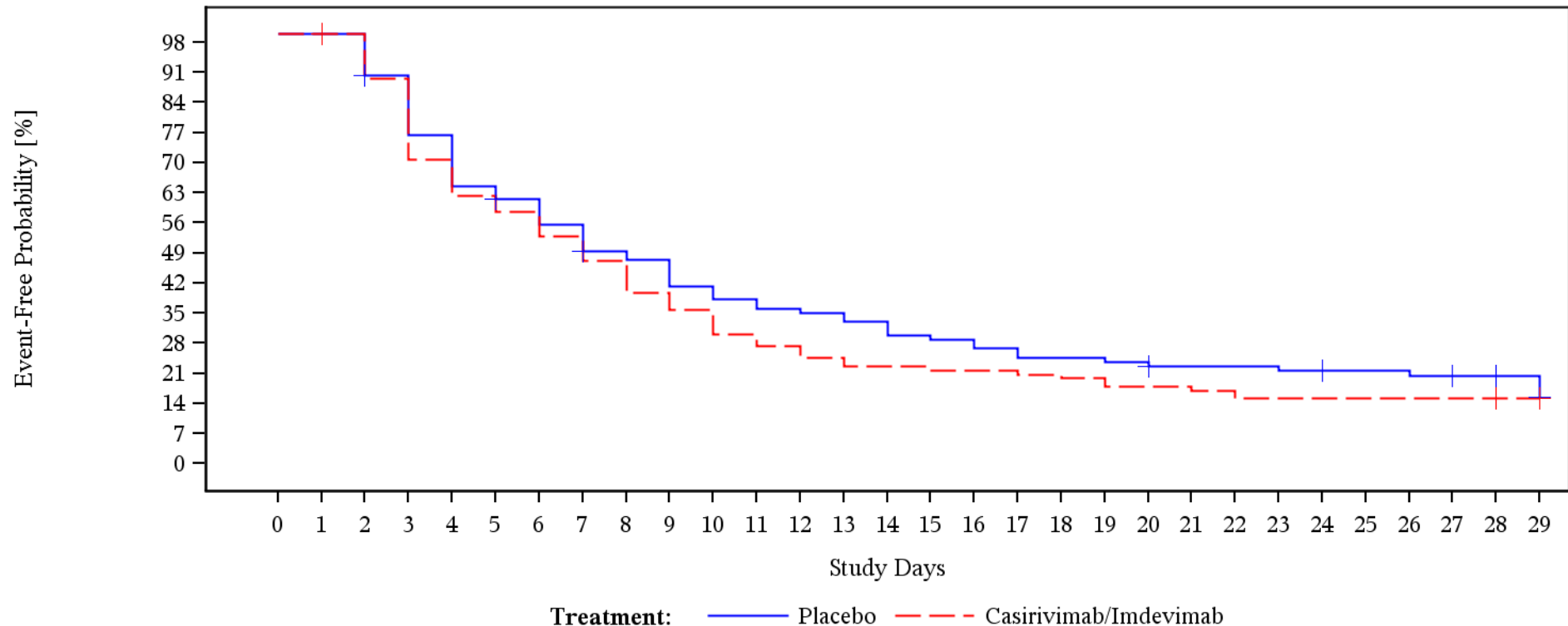
Placebo	125	125	44	42	40	32	30	27	26	23	21	21	20	18	18	18	18	17	17	15	15	15	14	14	14	14	14	14	14	9
Casirivimab/Imdevimab	119	119	32	29	26	26	24	23	23	21	18	17	15	15	14	14	13	13	13	11	11	11	11	11	10	10	10	10	10	7

Patients Censored

Placebo	0	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	82	82	82	82	82	82	82	82	82	82	82	87	96	
Casirivimab/Imdevimab	0	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	88	88	88	88	88	88	91	98

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

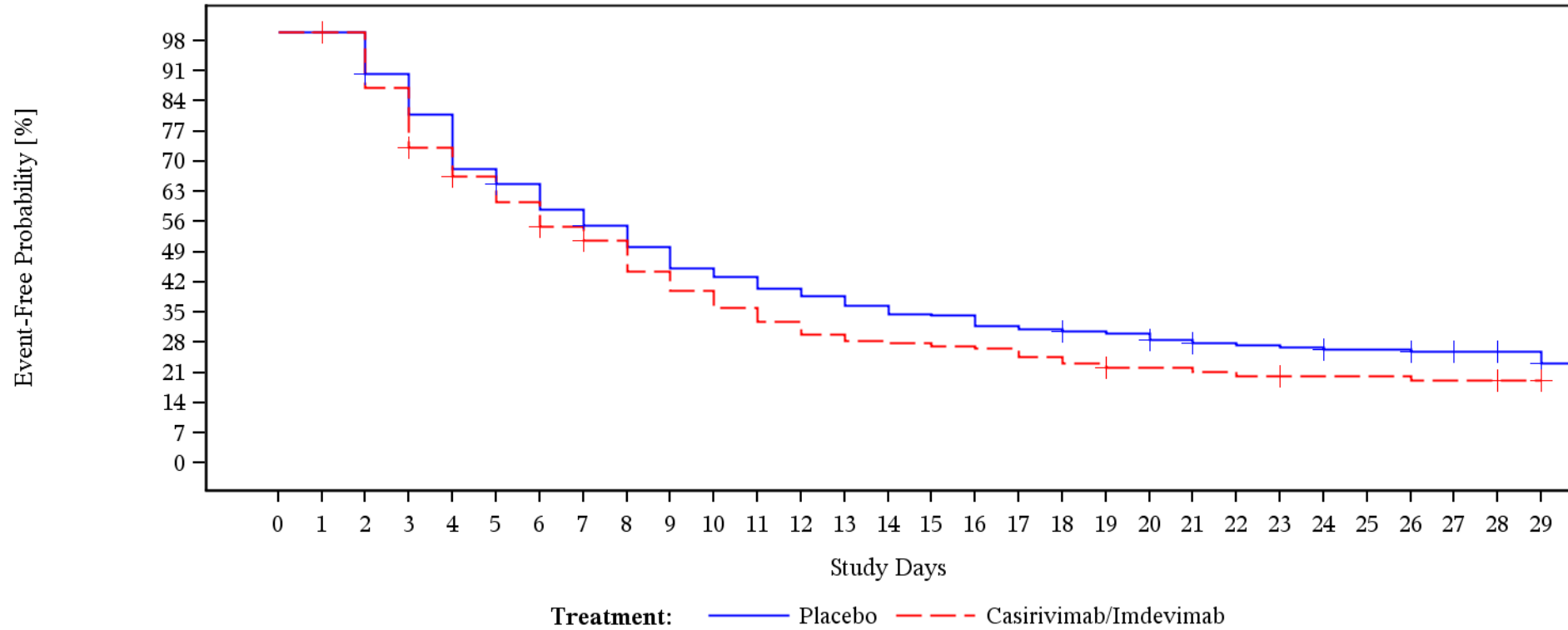
Placebo	346	346	104	91	77	65	61	55	48	46	40	37	35	34	32	29	28	26	24	24	23	21	21	21	20	19	19	18	17	8
Casirivimab/Imdevimab	363	363	106	95	75	66	62	56	50	42	38	32	29	26	24	24	23	23	22	21	19	19	18	16	16	16	16	16	16	6

Patients Censored

Placebo	0	242	245	245	245	246	246	247	247	247	247	247	247	247	247	247	247	247	247	247	248	248	248	248	249	249	249	250	259	265
Casirivimab/Imdevimab	0	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	257	267	273

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

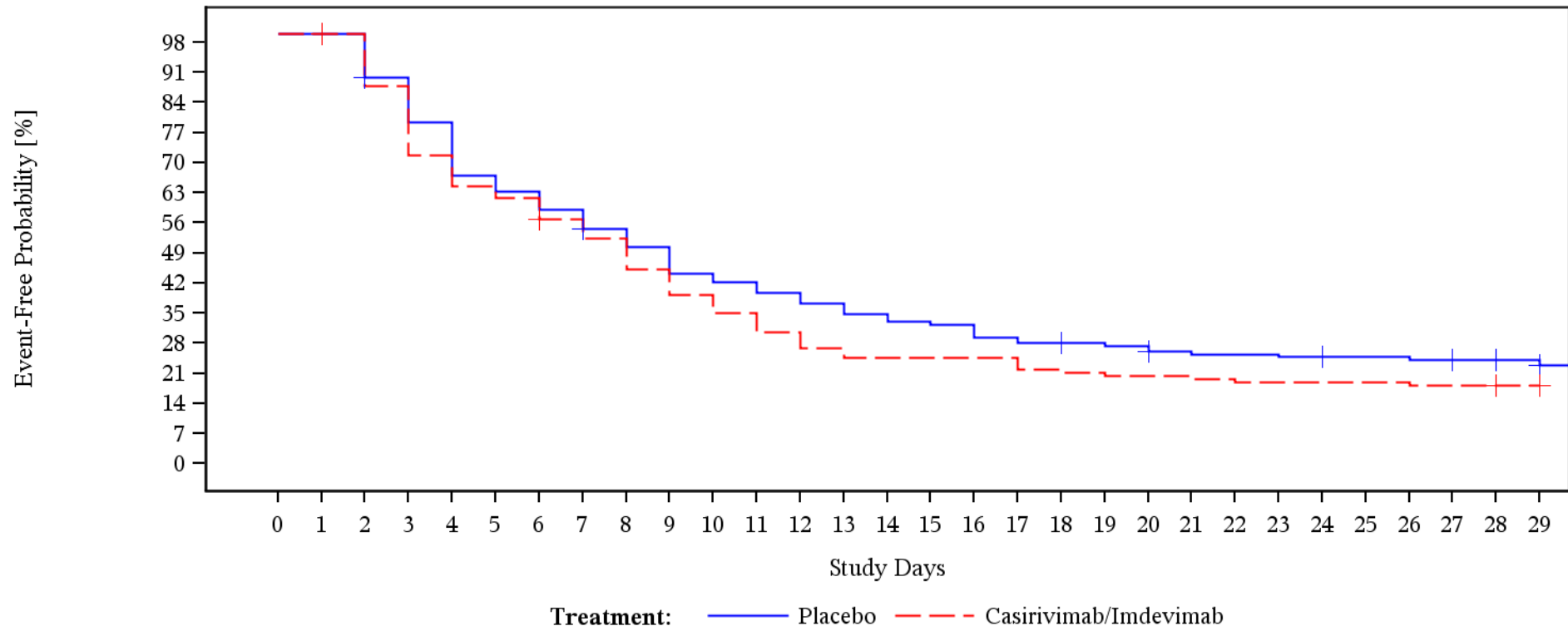
Placebo	711	711	226	201	180	152	143	130	121	110	99	95	89	85	80	76	75	70	68	66	65	61	58	57	56	54	54	51	49	28
Casirivimab/Imdevimab	698	698	216	188	157	142	129	115	107	92	83	75	68	62	59	58	56	55	51	48	45	45	43	41	39	39	39	37	37	18

Patients Censored

Placebo	0	485	488	488	488	489	489	490	490	490	490	490	490	490	490	490	490	490	491	491	492	493	493	493	494	494	496	498	519	543
Casirivimab/Imdevimab	0	482	482	483	484	484	486	487	487	487	487	487	487	487	487	487	487	487	487	488	488	488	488	490	490	490	490	490	509	527

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

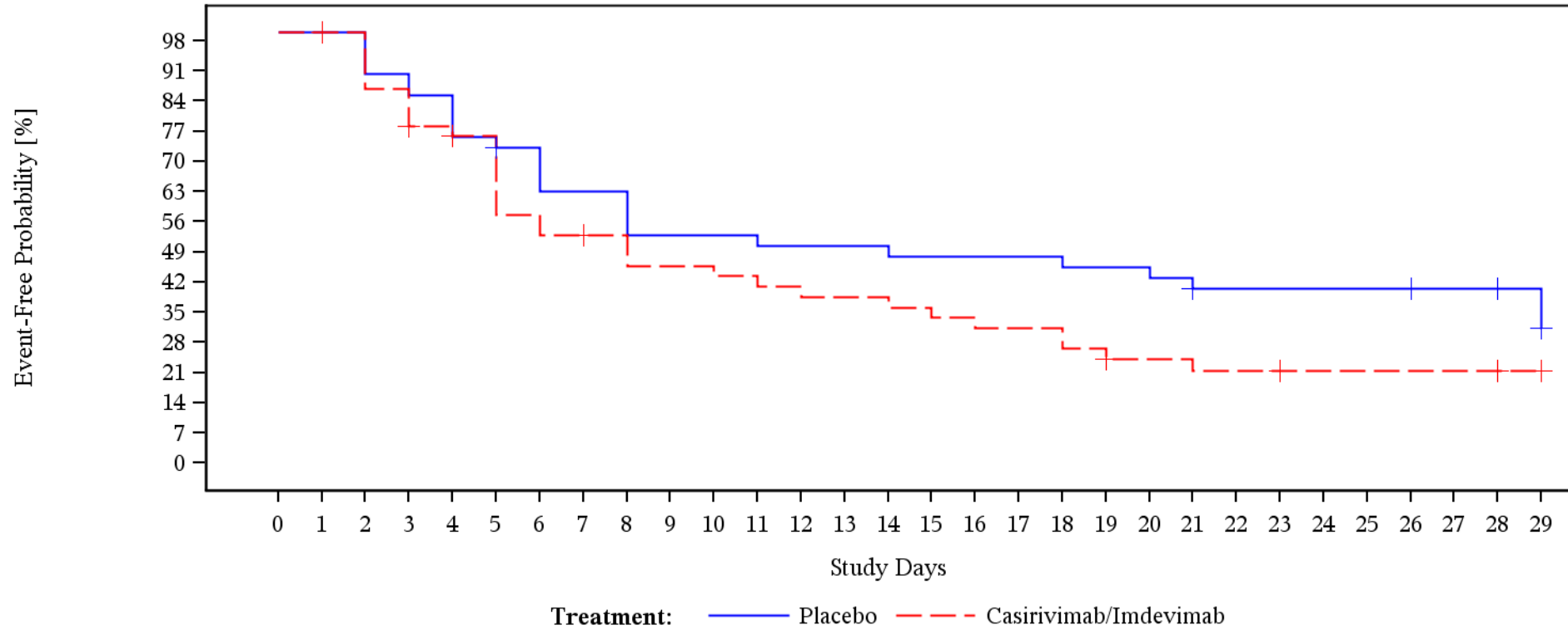
Placebo	519	519	166	146	129	109	103	96	88	81	71	68	64	60	56	53	52	47	45	44	43	40	39	39	38	37	37	36	34	18
Casirivimab/Imdevimab	500	500	141	124	101	91	87	78	72	62	54	48	42	37	34	34	34	34	30	29	28	28	27	26	26	26	26	25	25	12

Patients Censored

Placebo	0	353	356	356	356	356	357	357	357	357	357	357	357	357	357	357	357	357	358	358	359	359	359	359	360	360	360	362	378	394
Casirivimab/Imdevimab	0	359	359	359	359	359	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	361	374	386

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

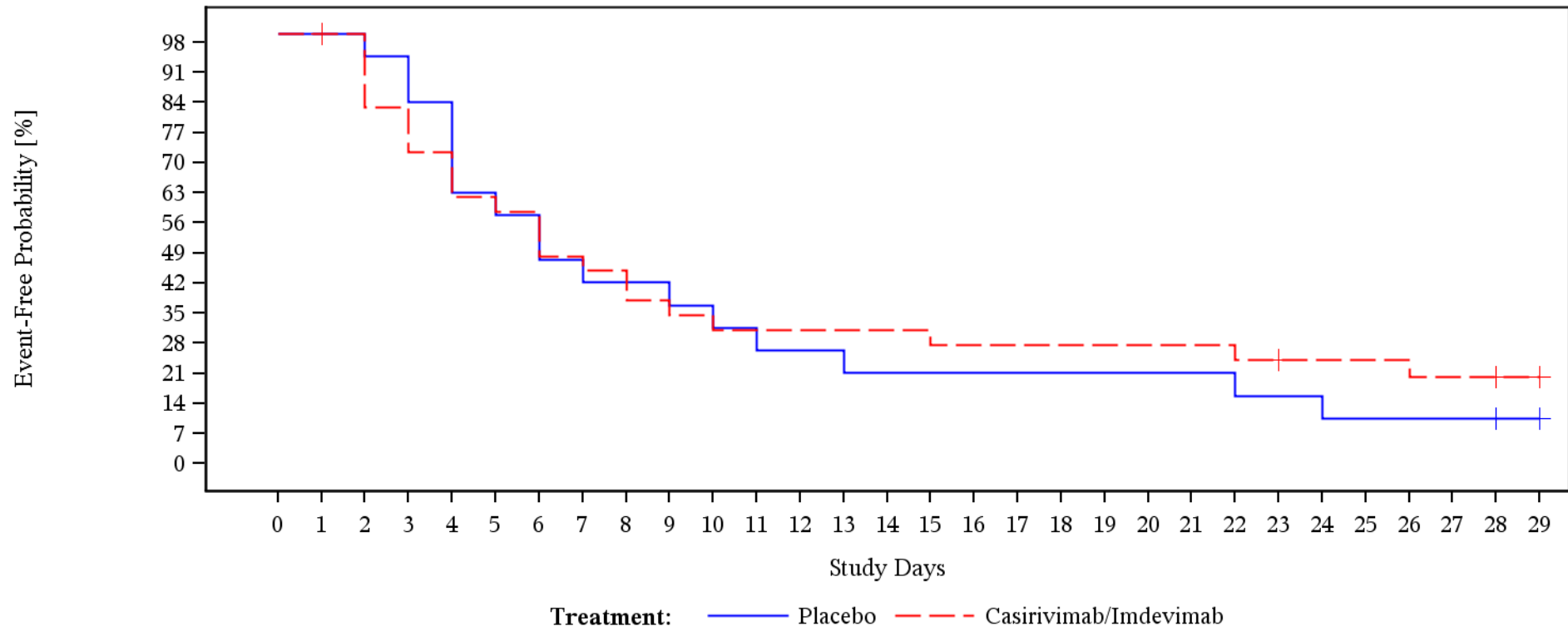
Placebo	164	164	41	37	35	31	29	25	25	21	21	21	20	20	20	19	19	19	19	18	18	17	15	15	15	15	15	13	13	9
Casirivimab/Imdevimab	177	177	46	40	35	33	25	23	22	19	19	18	17	16	16	15	14	13	13	11	9	9	8	8	7	7	7	7	7	4

Patients Censored

Placebo	0	123	123	123	123	124	124	124	124	124	124	124	124	124	124	124	124	124	124	124	125	125	125	125	125	127	127	131	138	
Casirivimab/Imdevimab	0	131	131	132	133	133	133	134	134	134	134	134	134	134	134	134	134	134	134	134	135	135	135	135	136	136	136	136	139	143

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	65	65	19	18	16	12	11	9	8	8	7	6	5	5	4	4	4	4	4	4	4	3	3	2	2	2	2	1
Casirivimab/Imdevimab	59	59	29	24	21	18	17	14	13	11	10	9	9	9	9	9	8	8	8	8	8	7	6	6	6	5	5	2

Patients Censored

Placebo	0	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	47	48	
Casirivimab/Imdevimab	0	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	31	31	31	31	31	31	34	36

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

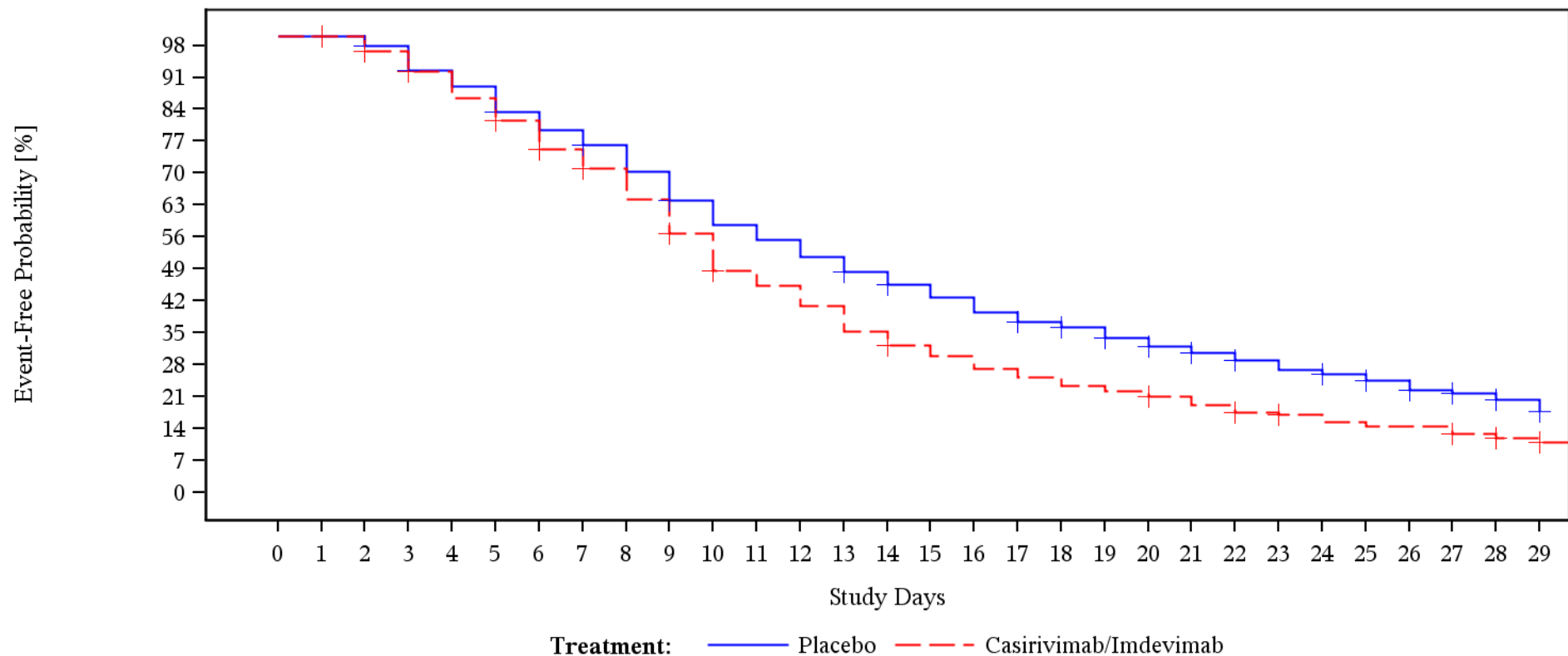
POPULATION: mFAS
 ENDPOINT: Time to first improvement (MID=15)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo											
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test						
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)						
All	n/a	736	100,0	171	23,2	565	76,8	3,00	3,00	4,00	8,00	6,00	9,00	748	100,0	167	22,3	581	77,7	4,00	NE	NE	9,00	7,00	10,00	0,1086	1,18	0,95	1,46	Convergence criterion (GCONV=1E-8) satisfied.							
Sex	Male	364	49,5	88	24,2	276	75,8	3,00	3,00	5,00	8,00	6,00	11,00	352	47,1	82	23,3	270	76,7	4,00	4,00	5,00	8,00	6,00	11,00	0,3830	1,14	0,84	1,54	Convergence criterion (GCONV=1E-8) satisfied.	0,7038						
	Female	372	50,5	83	22,3	289	77,7	3,00	3,00	4,00	7,00	5,00	8,00	396	52,9	85	21,5	311	78,5	4,00	3,00	4,00	9,00	6,00	11,00	0,1586	1,23	0,91	1,67	Convergence criterion (GCONV=1E-8) satisfied.							
Age	18-64	643	87,4	150	23,3	493	76,7	3,00	3,00	4,00	8,00	6,00	9,00	660	88,2	154	23,3	506	76,7	4,00	3,00	4,00	8,00	7,00	10,00	0,0883	1,21	0,96	1,51	Convergence criterion (GCONV=1E-8) satisfied.	0,9004						
	65-74	62	8,4	18	29,0	44	71,0	4,00	2,00	6,00	7,00	4,00	18,00	68	9,1	12	17,6	56	82,4	4,00	2,00	7,00	11,00	3,00	29,00	0,6984	1,15	0,55	2,41	Convergence criterion (GCONV=1E-8) satisfied.							
	>=75	31	4,2	3	9,7	28	90,3	2,00	2,00	NE	NE	2,00	NE	20	2,7	1	5,0	19	95,0	29,00	NE	NE	29,00	NE	NE	0,7150	1,50	0,16	14,42	Convergence criterion (GCONV=1E-8) satisfied.							
Baseline viral load categories	<=10^5 copies/mL	161	21,9	34	21,1	127	78,9	3,50	2,00	5,00	8,00	5,00	12,00	150	20,1	30	20,0	120	80,0	4,00	2,00	6,00	13,00	5,00	24,00	0,0876	1,50	0,92	2,47	Convergence criterion (GCONV=1E-8) satisfied.	0,5767						
	>10^5 copies/mL - <=10^6 copies/mL	91	12,4	26	28,6	65	71,4	3,00	2,00	5,00	6,00	4,00	11,00	123	16,4	27	22,0	96	78,0	4,00	2,00	8,00	8,50	5,00	11,00	0,9206	1,03	0,60	1,76	Convergence criterion (GCONV=1E-8) satisfied.							
	>10^6 copies/mL - <=10^7 copies/mL	119	16,2	21	17,6	98	82,4	5,50	2,00	9,00	11,00	8,00	NE	125	16,7	29	23,2	96	76,8	4,00	4,00	6,00	9,00	6,00	21,00	0,8229	0,94	0,54	1,65	Convergence criterion (GCONV=1E-8) satisfied.							
	>10^7 copies/mL	363	49,3	90	24,8	273	75,2	3,00	3,00	4,00	7,00	5,00	8,00	346	46,3	81	23,4	265	76,6	4,00	3,00	4,00	7,00	6,00	10,00	0,3365	1,15	0,85	1,55	Convergence criterion (GCONV=1E-8) satisfied.							
	Unknown	2	0,3	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	4	0,5	0	0,0	4	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Country	USA	698	94,8	171	24,5	527	75,5	3,00	3,00	4,00	8,00	6,00	9,00	711	95,1	167	23,5	544	76,5	4,00	NE	NE	9,00	7,00	10,00	0,1086	1,18	0,95	1,46	Convergence criterion (GCONV=1E-8) satisfied.							
	MEX	38	5,2	0	0,0	38	100,0	NE	NE	NE	NE	NE	NE	37	4,9	0	0,0	37	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Baseline serostatus	Negative	500	67,9	114	22,8	386	77,2	3,00	3,00	4,00	8,00	6,00	9,00	519	69,4	124	23,9	395	76,1	4,00	3,00	4,00	9,00	7,00	10,00	0,1926	1,17	0,91	1,52	Convergence criterion (GCONV=1E-8) satisfied.	0,5006						
	Positive	177	24,0	34	19,2	143	80,8	5,00	2,00	5,00	8,00	5,00	15,00	164	21,9	26	15,9	138	84,1	5,00	3,00	8,00	14,00	6,00	29,00	0,1316	1,46	0,87	2,44	Convergence criterion (GCONV=1E-8) satisfied.							
	Other	59	8,0	23	39,0	36	61,0	3,00	2,00	5,00	6,00	4,00	10,00	65	8,7	17	26,2	48	73,8	4,00	2,00	6,00	6,00	4,00	11,00	0,6912	0,89	0,47	1,66	Convergence criterion (GCONV=1E-8) satisfied.							

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-7-eff-tte-ttimp15

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	381	371	350	336	313	298	284	262	238	218	206	192	179	167	157	145	136	131	122	114	108	101	94	90	84	76	68	40
Casirivimab/Imdevimab	736	736	376	363	345	323	304	279	263	238	209	178	166	150	129	116	108	98	91	84	80	75	68	61	57	51	48	48	40	24

Patients Censored

Placebo	0	367	369	370	370	372	372	374	374	375	375	375	375	376	377	377	377	378	379	380	381	382	383	383	384	385	386	391	415	450
Casirivimab/Imdevimab	0	360	361	362	362	363	364	365	365	366	367	367	367	367	369	369	369	369	369	369	370	370	371	374	374	374	374	377	390	411

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-ttrtuh.pdf

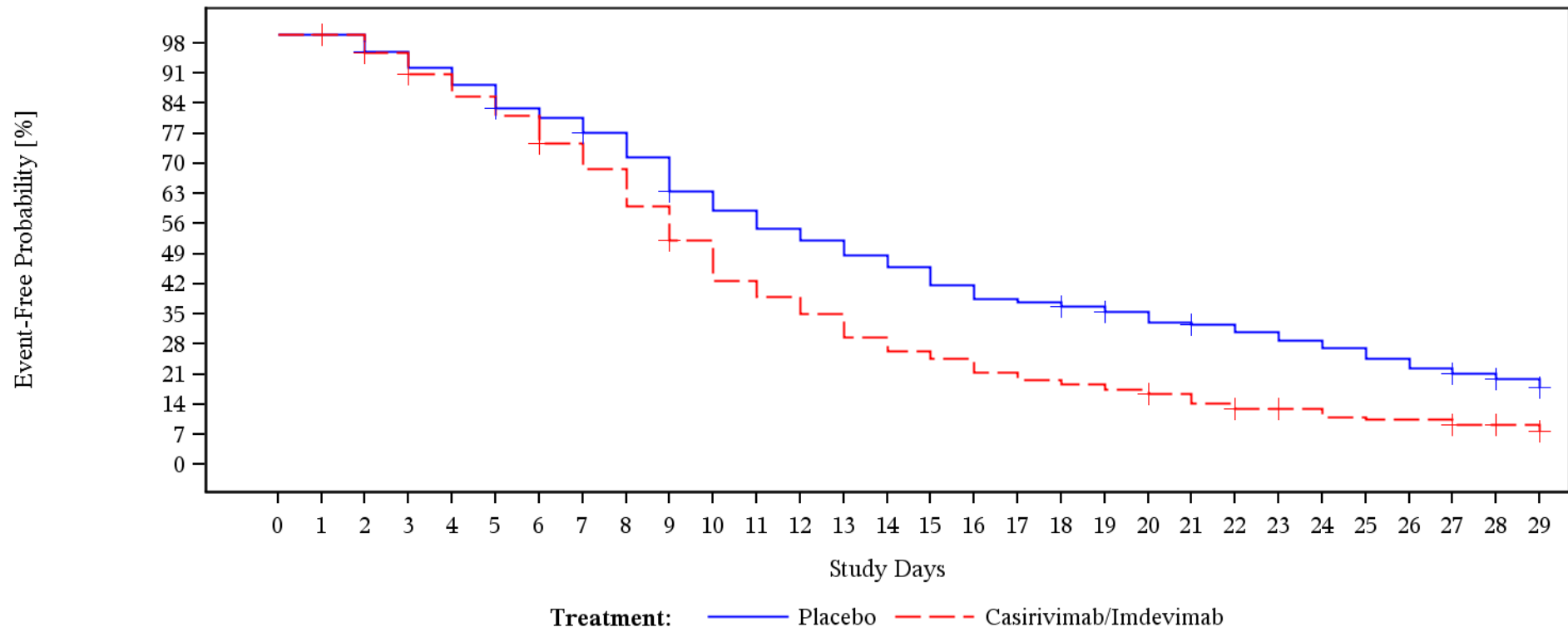
POPULATION: mFAS
 ENDPOINT: Time to return to usual health
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	324	44,0	412	56,0	7,00	6,00	8,00	10,00	10,00	12,00	748	100,0	298	39,8	450	60,2	8,00	6,00	8,00	13,00	12,00	15,00	0,0003	1,32	1,13	1,55	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-8-eff-tte-ttrtuh

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

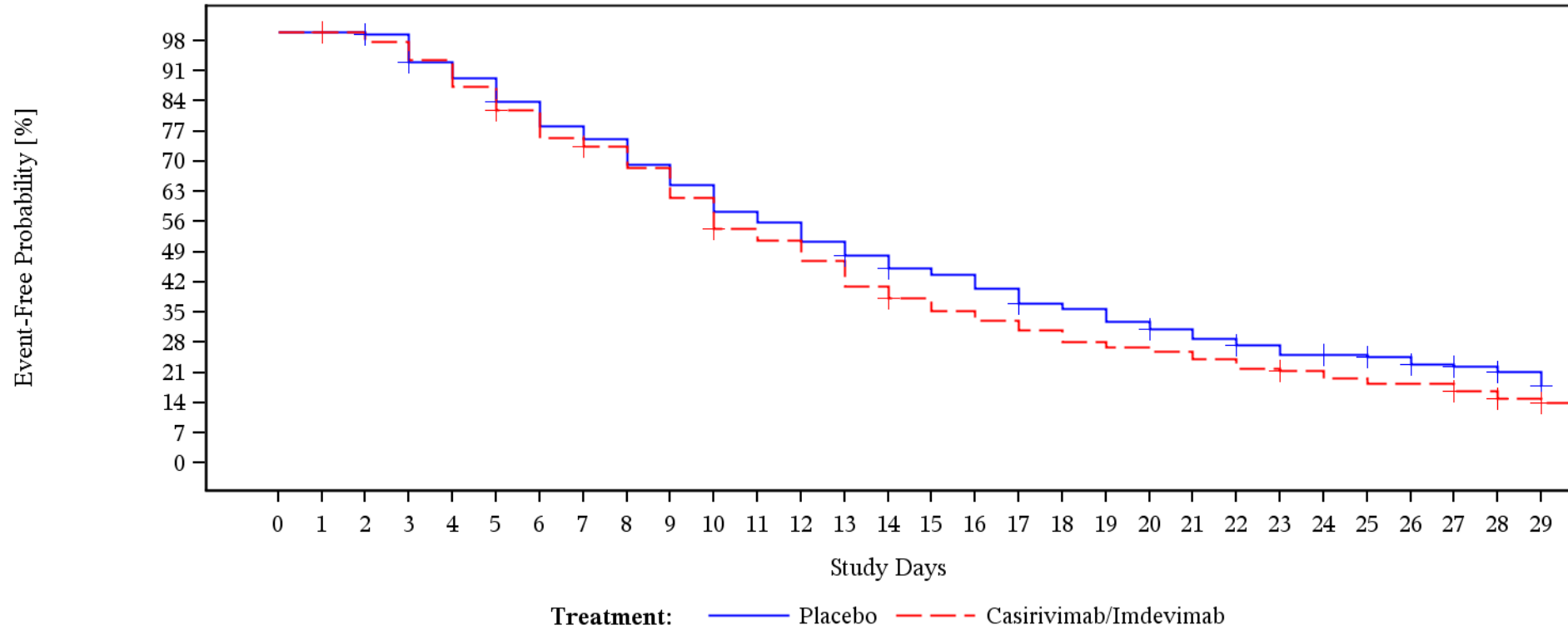
Placebo	352	352	181	173	166	159	148	144	136	126	111	103	96	91	85	80	73	67	66	63	60	56	54	51	48	45	41	37	33	20
Casirivimab/Imdevimab	364	364	188	179	169	159	151	138	127	111	95	78	71	64	54	48	45	39	36	34	32	29	25	22	20	17	16	16	13	7

Patients Censored

Placebo	0	171	172	172	172	173	173	175	175	176	176	176	176	176	176	176	176	176	176	177	178	178	179	179	179	179	179	179	181	192	210
Casirivimab/Imdevimab	0	176	177	178	178	178	179	179	179	180	180	180	180	180	180	180	180	180	180	180	180	181	181	182	184	184	184	184	185	191	197

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

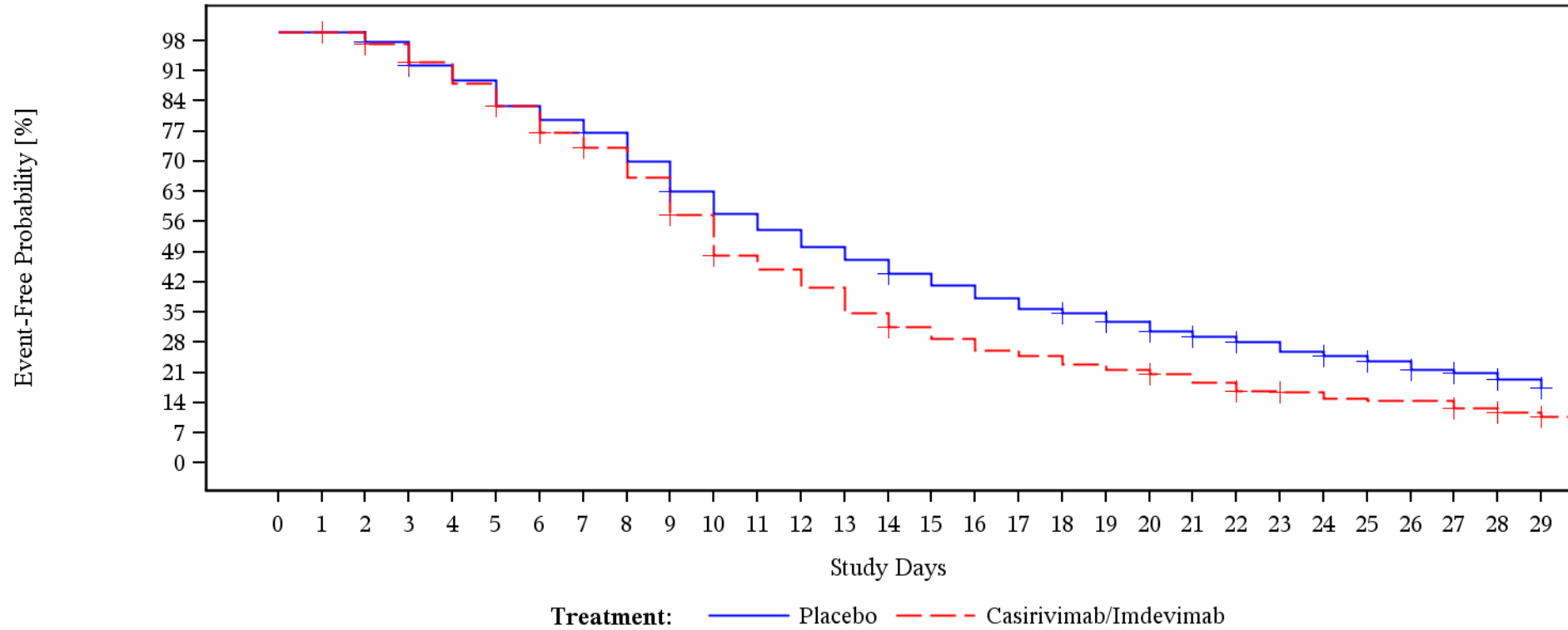
Placebo	396	396	200	198	184	177	165	154	148	136	127	115	110	101	94	87	84	78	70	68	62	58	54	50	46	45	43	39	35	20
Casirivimab/Imdevimab	372	372	188	184	176	164	153	141	136	127	114	100	95	86	75	68	63	59	55	50	48	46	43	39	37	34	32	32	27	17

Patients Censored

Placebo	0	196	197	198	198	199	199	199	199	199	199	199	199	200	201	201	201	202	202	202	203	203	204	204	205	206	207	210	223	240
Casirivimab/Imdevimab	0	184	184	184	184	185	185	186	186	186	187	187	187	187	189	189	189	189	189	189	189	189	189	190	190	190	190	192	199	214

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

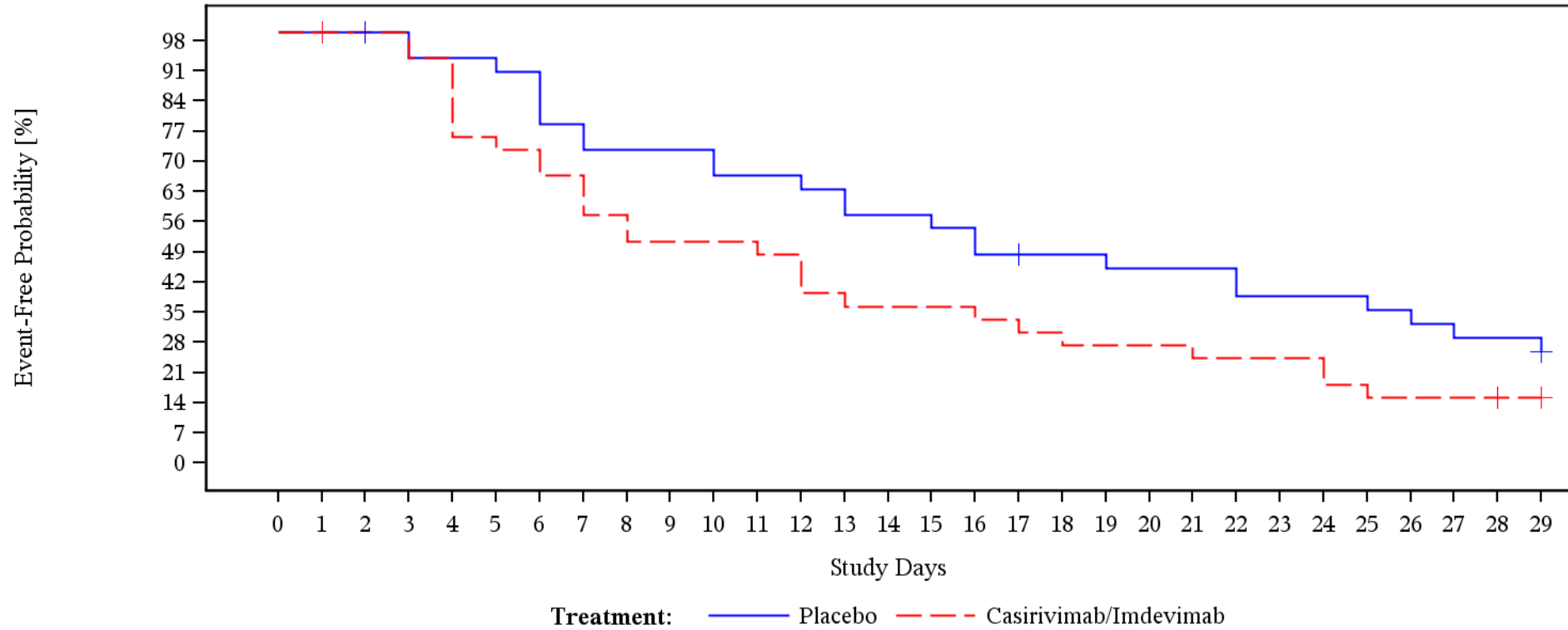
Placebo	660	660	340	331	312	300	279	268	256	234	210	192	180	167	157	145	136	126	118	114	106	98	93	88	81	77	72	65	58	30
Casirivimab/Imdevimab	643	643	331	321	306	290	272	250	238	215	186	155	144	131	112	99	91	82	78	72	68	64	58	51	47	43	41	41	33	22

Patients Censored

Placebo	0	320	321	322	322	323	323	325	325	326	326	326	326	326	327	327	327	327	328	329	330	331	332	332	333	334	335	340	364	391
Casirivimab/Imdevimab	0	312	313	314	314	315	316	317	317	318	319	319	319	319	321	321	321	321	321	321	322	322	323	326	326	326	326	329	338	357

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

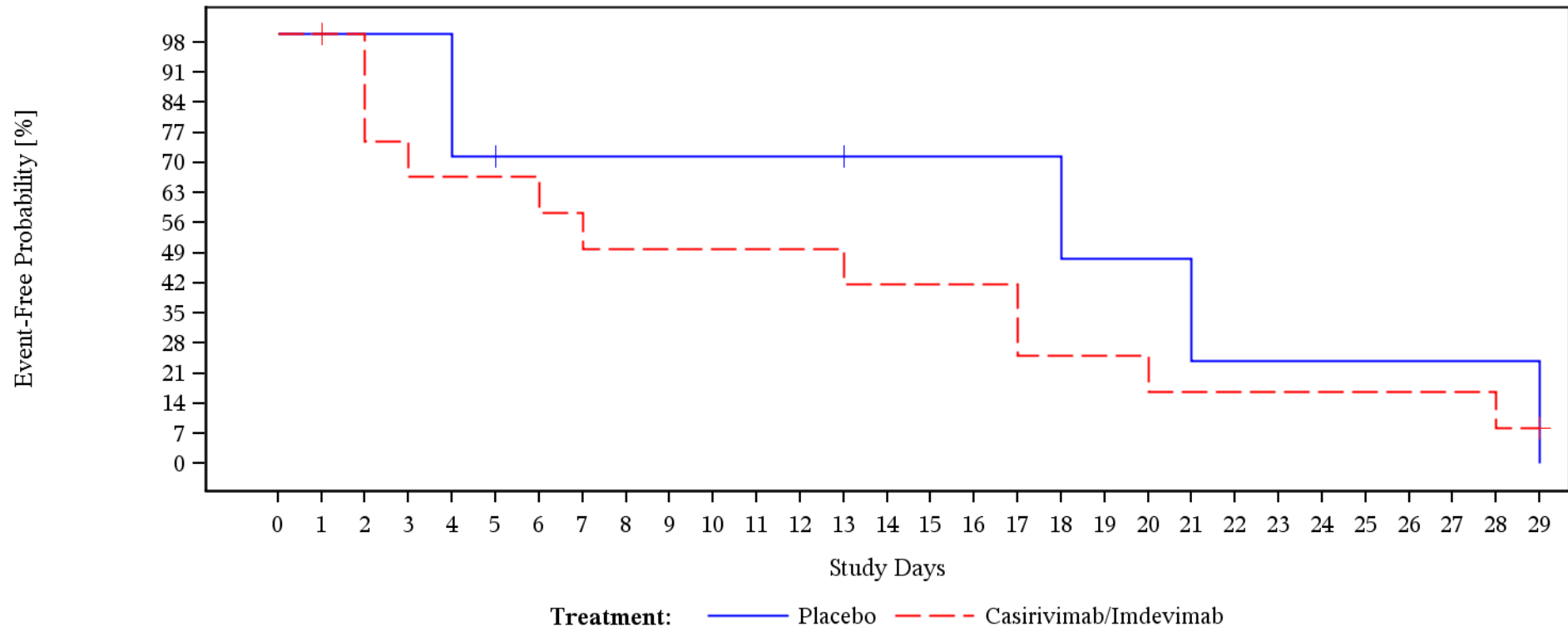
Placebo	68	68	34	33	31	31	30	26	24	24	24	22	22	21	19	19	18	16	15	15	14	14	14	12	12	12	11	10	9	9
Casirivimab/Imdevimab	62	62	33	33	31	25	24	22	19	17	17	17	16	13	12	12	12	11	10	9	9	9	8	8	8	6	5	5	5	1

Patients Censored

Placebo	0	34	35	35	35	35	35	35	35	35	35	35	35	35	35	35	35	35	36	36	36	36	36	36	36	36	36	36	36	44
Casirivimab/Imdevimab	0	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	33	34

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

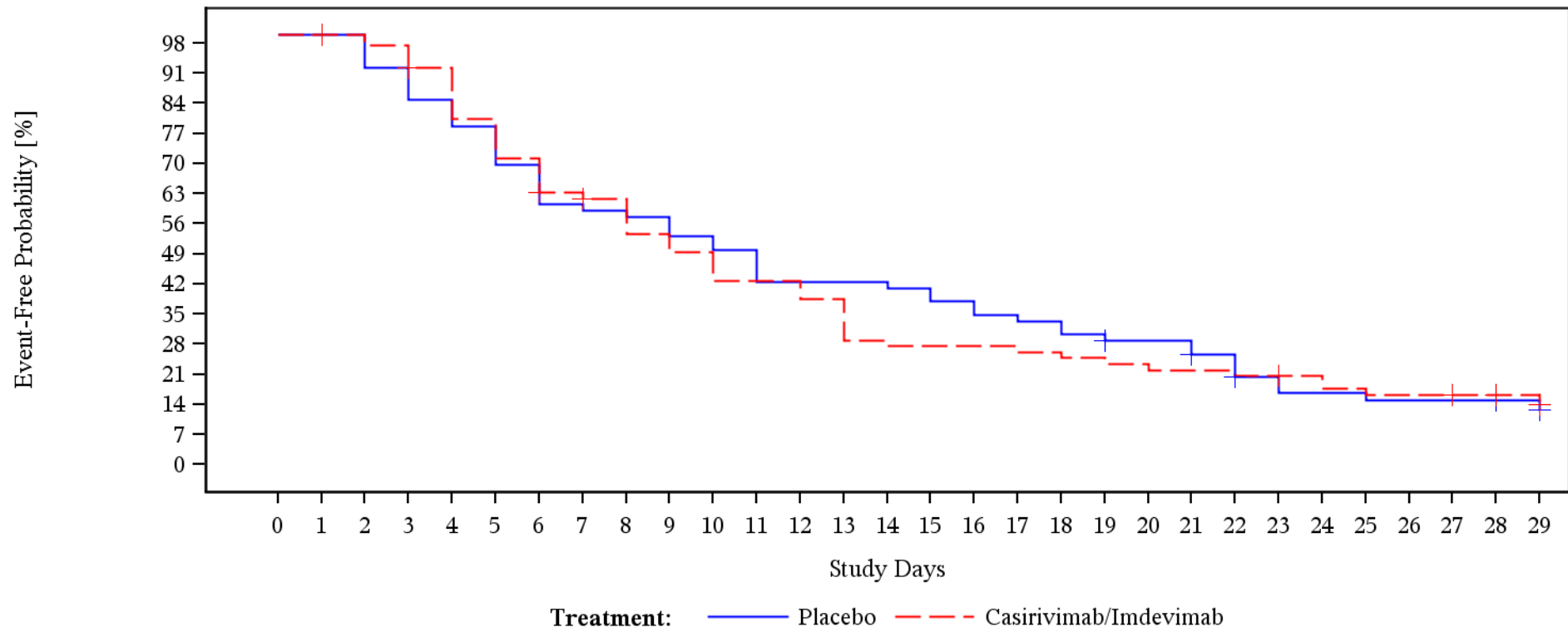
Placebo	20	20	7	7	7	5	4	4	4	4	4	4	4	3	3	3	3	3	2	2	2	1	1	1	1	1	1	1	1
Casirivimab/Imdevimab	31	31	12	9	8	8	8	7	6	6	6	6	6	5	5	5	5	3	3	3	2	2	2	2	2	2	2	2	1

Patients Censored

Placebo	0	13	13	13	13	14	14	14	14	14	14	14	14	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Casirivimab/Imdevimab	0	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	20

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

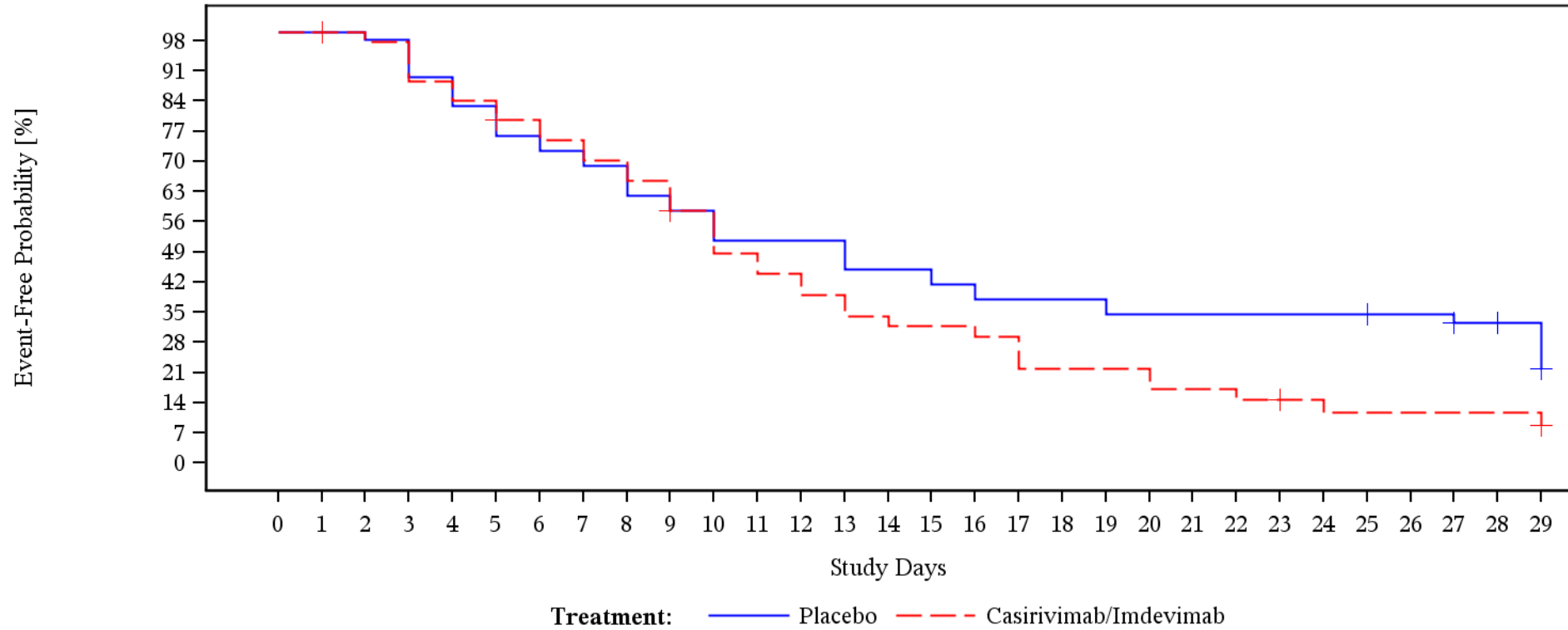
Placebo	150	150	66	61	56	52	46	40	39	38	35	33	28	28	28	27	25	23	22	20	18	18	15	11	9	9	8	8	8	7
Casirivimab/Imdevimab	161	161	77	75	70	61	54	47	45	39	36	31	31	28	21	20	20	20	19	18	17	16	16	15	14	12	11	11	9	7

Patients Censored

Placebo	0	84	84	84	84	84	84	84	84	84	84	84	84	84	84	84	84	84	84	85	85	86	87	87	87	87	87	87	87	88	94
Casirivimab/Imdevimab	0	84	84	85	85	85	86	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	88	88	88	88	90	92	98	

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

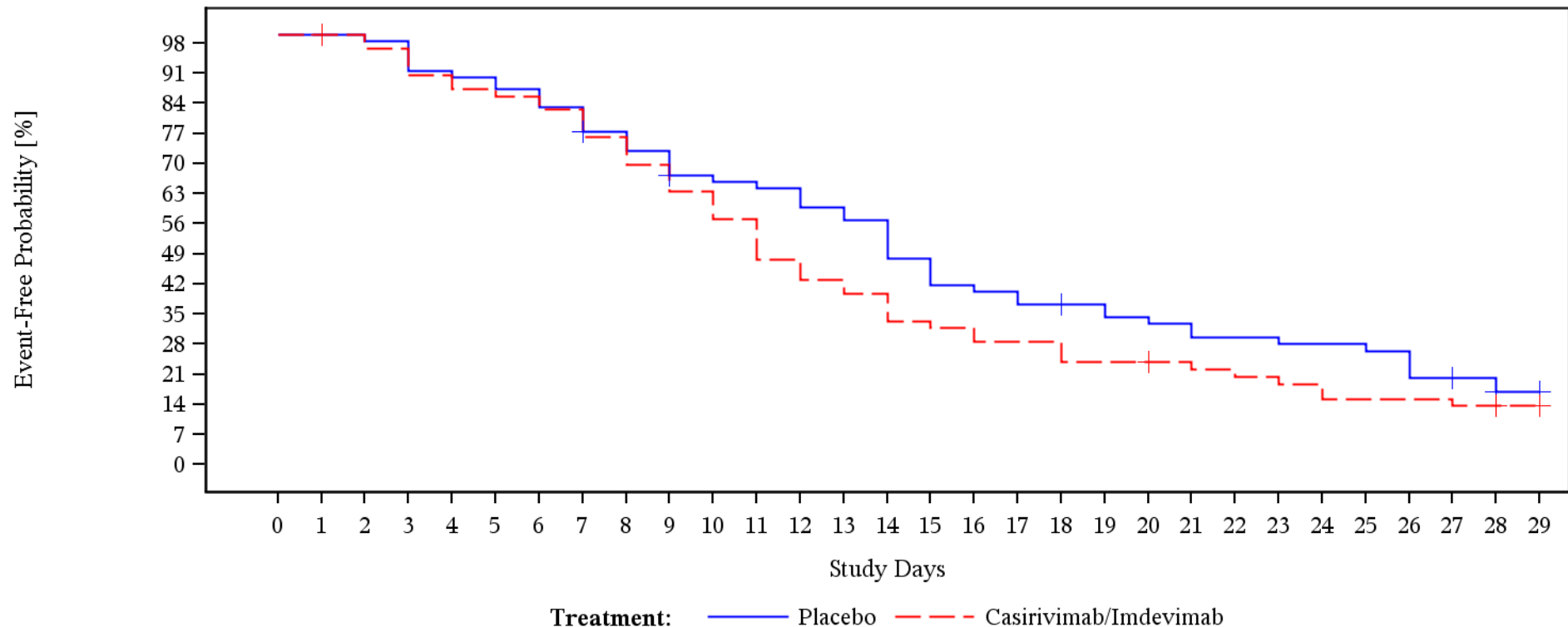
Placebo	123	123	58	57	52	48	44	42	40	36	34	30	30	30	26	26	24	22	22	22	20	20	20	20	20	19	19	17	9	
Casirivimab/Imdevimab	91	91	44	43	39	37	34	32	30	28	24	20	18	16	14	13	13	12	9	9	9	7	7	6	5	4	4	4	4	4

Patients Censored

Placebo	0	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	66	66	67	75	81
Casirivimab/Imdevimab	0	47	47	47	47	48	48	48	48	49	49	49	49	49	49	49	49	49	49	49	49	49	49	49	50	50	50	50	50	53

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

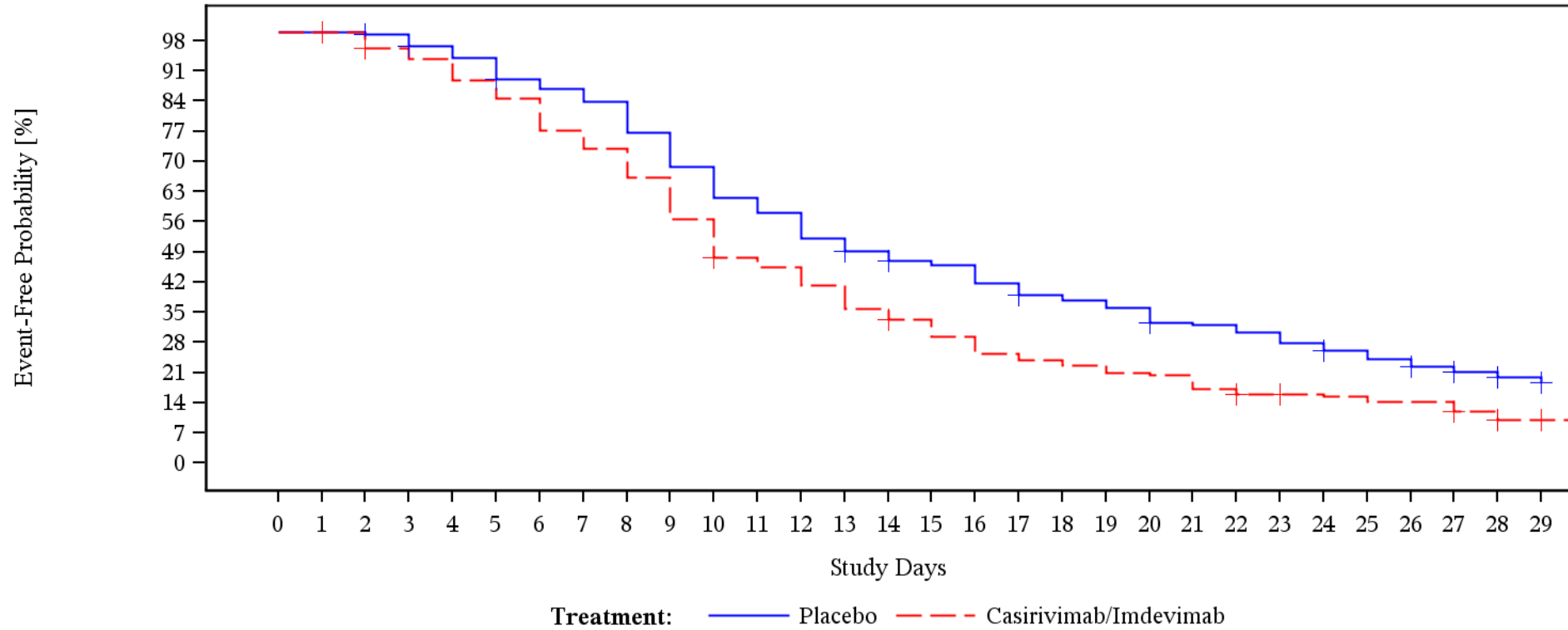
Placebo	125	125	71	70	65	64	62	59	53	50	45	44	43	40	38	32	28	27	25	24	22	21	19	19	18	18	17	13	12	6
Casirivimab/Imdevimab	119	119	63	61	57	55	54	52	48	44	40	36	30	27	25	21	20	18	18	15	15	14	13	12	11	9	9	9	8	4

Patients Censored

Placebo	0	54	54	54	54	54	54	56	56	57	57	57	57	57	57	57	57	57	57	58	58	58	58	58	58	58	58	58	59	63	69	
Casirivimab/Imdevimab	0	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	57	57	57	57	57	57	57	57	57	61	65

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

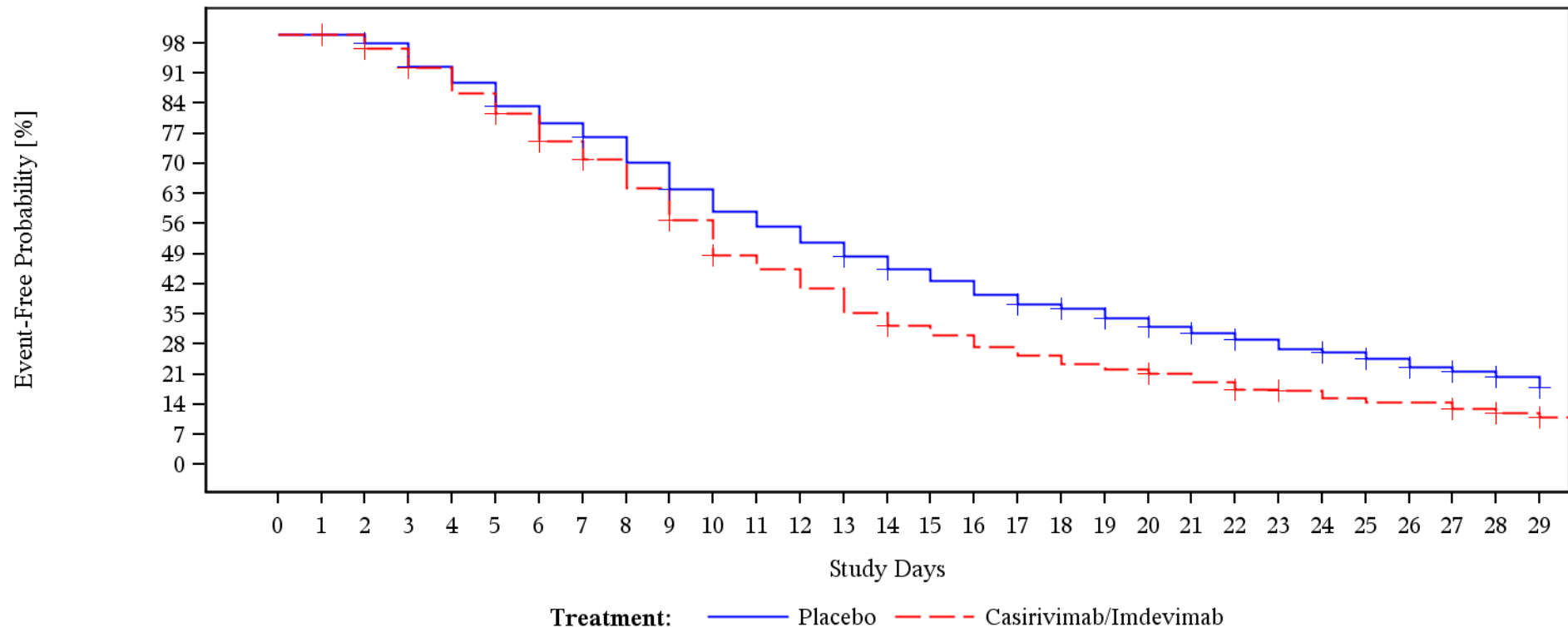
Placebo	346	346	184	181	175	170	159	155	150	137	123	110	104	93	87	82	80	73	67	65	62	55	54	51	47	43	40	36	31	18
Casirivimab/Imdevimab	363	363	190	182	177	168	160	146	138	125	107	89	85	77	67	60	53	46	43	41	38	37	31	28	27	26	24	24	19	9

Patients Censored

Placebo	0	162	164	165	165	167	167	167	167	167	167	167	167	168	169	169	169	170	170	170	171	171	171	171	172	172	173	176	187	204	
Casirivimab/Imdevimab	0	173	174	174	174	174	174	174	174	174	175	175	175	175	177	177	177	177	177	177	177	177	177	178	179	179	179	179	180	187	195

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

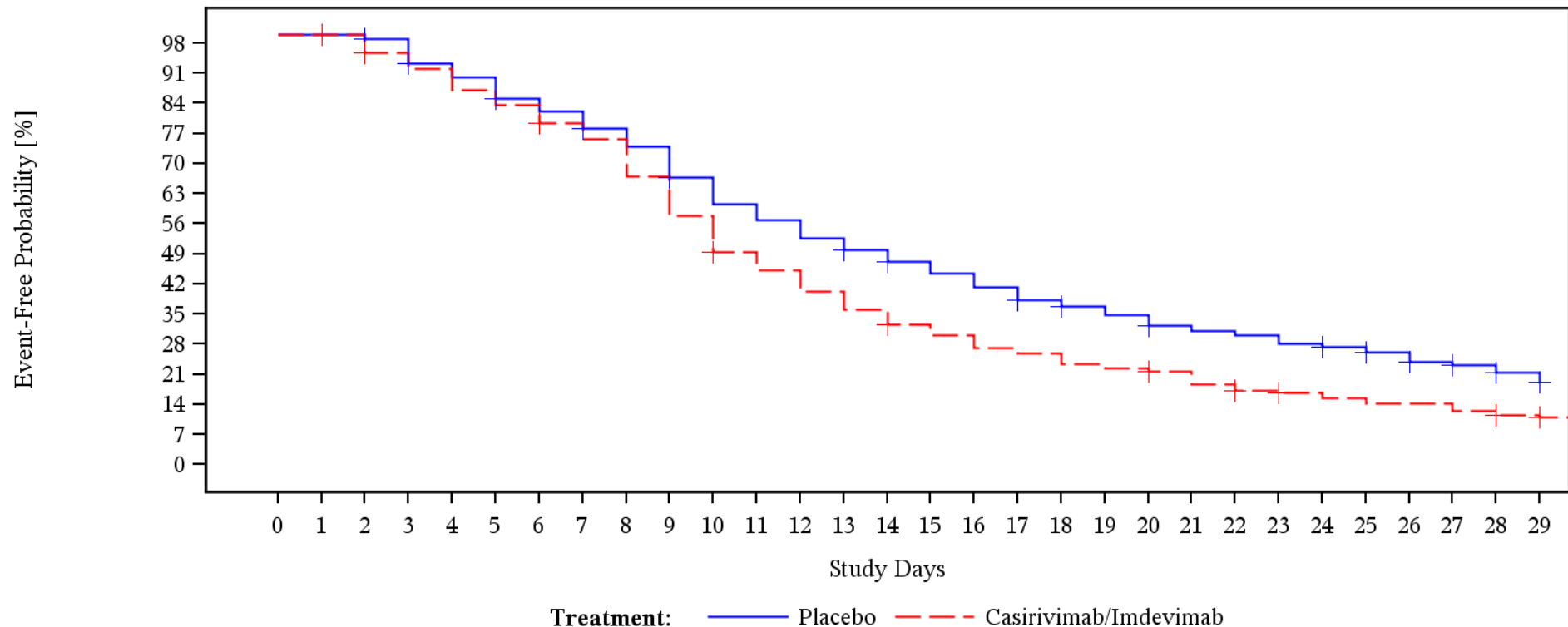
Placebo	711	711	381	371	350	336	313	298	284	262	238	218	206	192	179	167	157	145	136	131	122	114	108	101	94	90	84	76	68	40
Casirivimab/Imdevimab	698	698	376	363	345	323	304	279	263	238	209	178	166	150	129	116	108	98	91	84	80	75	68	61	57	51	48	48	40	24

Patients Censored

Placebo	0	330	332	333	333	335	335	337	337	338	338	338	338	339	340	340	340	341	342	343	344	345	346	346	347	348	349	354	378	413	
Casirivimab/Imdevimab	0	322	323	324	324	325	326	327	327	328	329	329	329	329	331	331	331	331	331	331	331	332	332	333	336	336	336	336	339	352	373

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

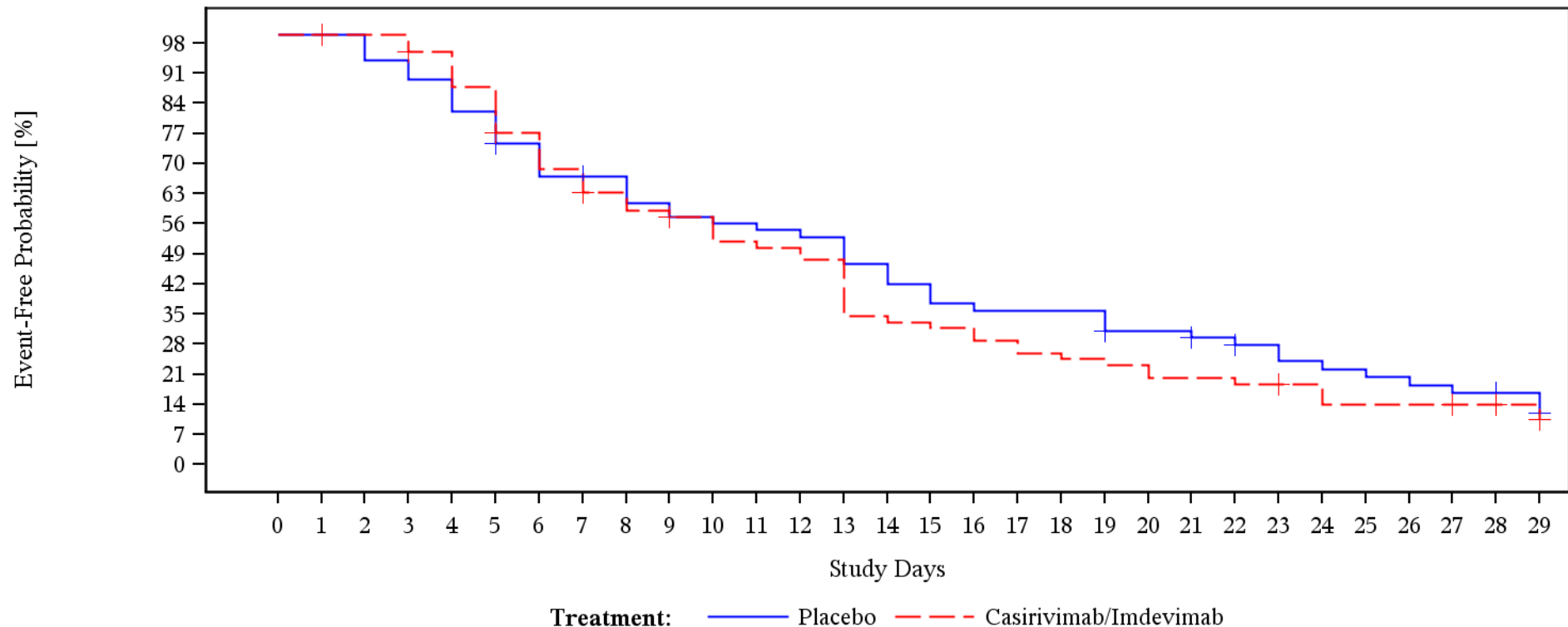
Placebo	519	519	283	278	261	252	237	229	217	205	184	167	157	145	137	128	121	112	103	98	93	85	82	79	74	71	67	60	53	31
Casirivimab/Imdevimab	500	500	263	251	241	228	219	207	197	175	151	128	117	104	93	83	77	69	66	60	57	54	47	42	39	36	33	33	29	19

Patients Censored

Placebo	0	236	238	239	239	240	240	241	241	242	242	242	242	243	244	244	244	245	246	246	247	247	247	247	248	249	250	255	273	301	
Casirivimab/Imdevimab	0	237	238	238	238	238	239	239	239	239	240	240	240	240	241	241	241	241	241	241	241	242	242	243	245	245	245	245	245	253	270

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

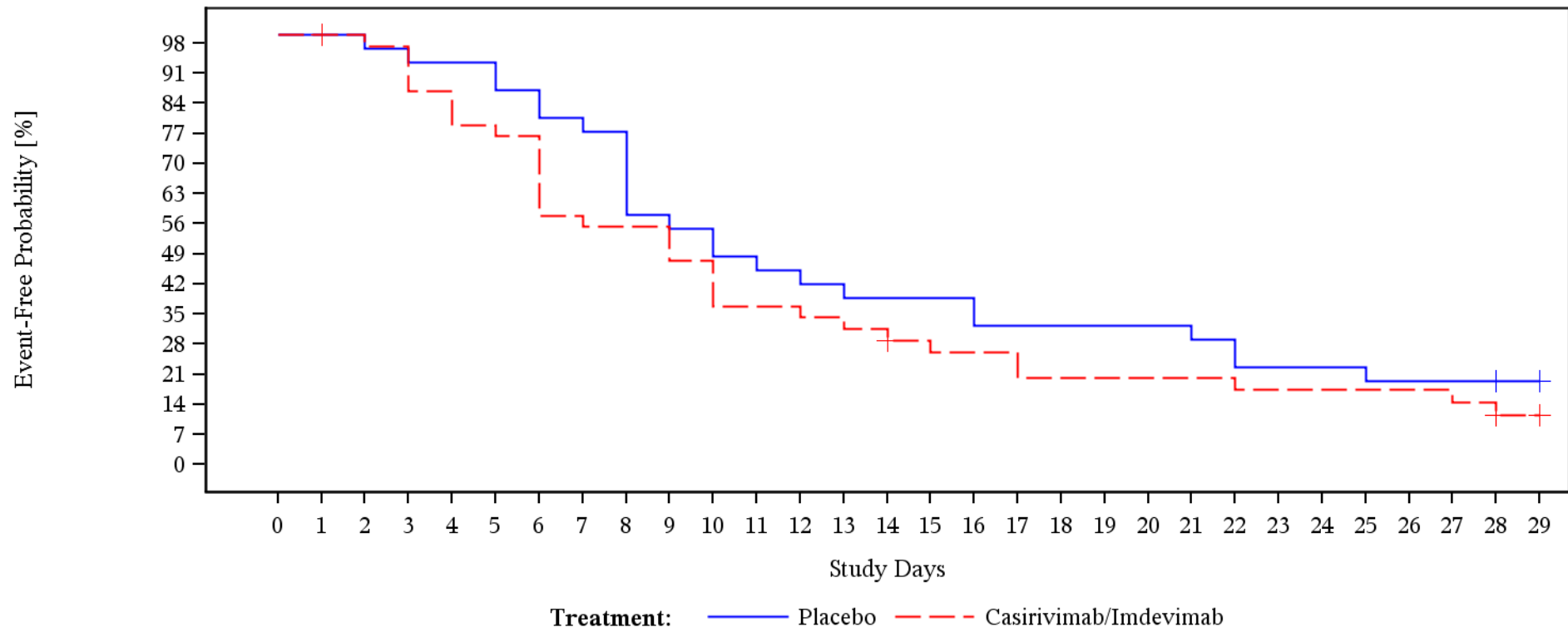
Placebo	164	164	67	63	60	55	49	44	43	39	37	36	35	34	30	27	24	23	23	23	19	19	17	15	13	12	11	10	9	7
Casirivimab/Imdevimab	177	177	75	75	71	65	56	50	45	42	40	36	35	33	24	23	22	20	18	17	16	14	14	13	12	9	9	9	6	4

Patients Censored

Placebo	0	97	97	97	97	98	98	99	99	99	99	99	99	99	99	99	99	99	99	100	100	101	102	102	102	102	102	102	104	109
Casirivimab/Imdevimab	0	102	102	103	103	104	104	105	105	106	106	106	106	106	106	106	106	106	106	106	106	106	106	107	107	107	107	110	112	115

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	65	65	31	30	29	29	27	25	24	18	17	15	14	13	12	12	12	10	10	10	10	10	9	7	7	7	6	6	6	2
Casirivimab/Imdevimab	59	59	38	37	33	30	29	22	21	21	18	14	14	13	12	10	9	9	7	7	7	7	7	6	6	6	6	6	5	1

Patients Censored

Placebo	0	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	38	40	
Casirivimab/Imdevimab	0	21	21	21	21	21	21	21	21	21	21	21	21	21	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	25	26

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

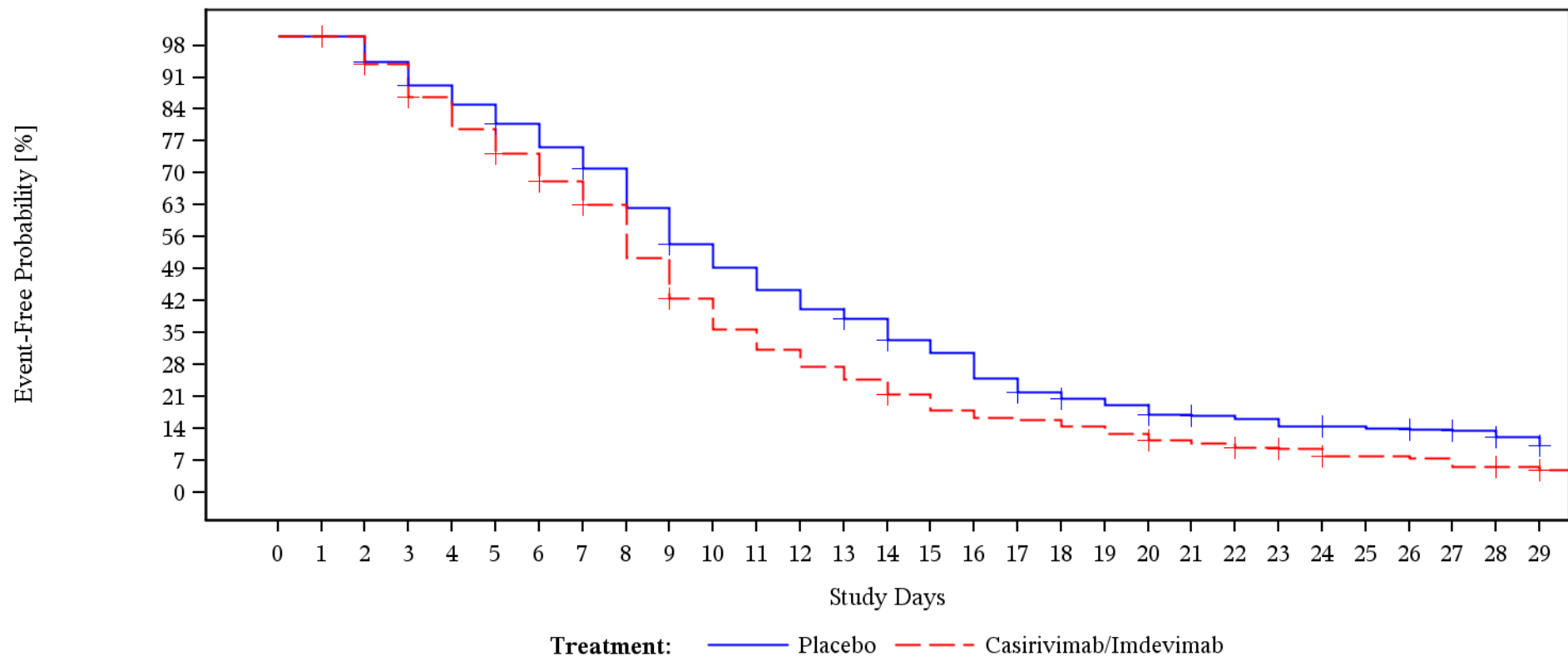
POPULATION: mFAS
 ENDPOINT: Time to return to usual health
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo						Casirivimab/Imdevimab vs. Placebo						Interaction Test								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event							log-rank p-value	Hazard Ratio			p-value (likelihood ratio)			
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median			Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		
All	n/a	736	100,0	324	44,0	412	56,0	7,00	6,00	8,00	10,00	10,00	12,00	748	100,0	298	39,8	450	60,2	8,00	6,00	8,00	13,00	12,00	15,00	0,0003	1,32	1,13	1,55	Convergence criterion (GCONV=1E-8) satisfied.				
Sex	Male	364	49,5	167	45,9	197	54,1	6,00	5,00	7,00	10,00	9,00	10,00	352	47,1	142	40,3	210	59,7	8,00	6,00	9,00	13,00	11,00	15,00	0,0001	1,53	1,22	1,91	Convergence criterion (GCONV=1E-8) satisfied.	0,0926			
	Female	372	50,5	157	42,2	215	57,8	7,00	6,00	8,00	12,00	10,00	13,00	396	52,9	156	39,4	240	60,6	8,00	6,00	9,00	13,00	11,00	16,00	0,1691	1,16	0,93	1,45	Convergence criterion (GCONV=1E-8) satisfied.				
Age	18-64	643	87,4	285	44,3	358	55,7	7,00	6,00	8,00	10,00	10,00	12,00	660	88,2	269	40,8	391	59,2	8,00	6,00	8,00	13,00	11,00	14,00	0,0019	1,29	1,09	1,52	Convergence criterion (GCONV=1E-8) satisfied.	0,6878			
	65-74	62	8,4	28	45,2	34	54,8	5,00	4,00	7,00	11,00	6,00	16,00	68	9,1	24	35,3	44	64,7	7,00	5,00	13,00	16,00	10,00	26,00	0,0768	1,62	0,93	2,80	Convergence criterion (GCONV=1E-8) satisfied.				
	>=75	31	4,2	11	35,5	20	64,5	2,50	2,00	7,00	10,00	2,00	20,00	20	2,7	5	25,0	15	75,0	4,00	4,00	21,00	18,00	4,00	29,00	0,4144	1,54	0,53	4,45	Convergence criterion (GCONV=1E-8) satisfied.				
Baseline viral load categories	<=10^5 copies/mL	161	21,9	63	39,1	98	60,9	5,00	4,00	6,00	9,00	7,00	12,00	150	20,1	56	37,3	94	62,7	5,00	3,00	6,00	10,50	6,00	15,00	0,8844	1,03	0,72	1,47	Convergence criterion (GCONV=1E-8) satisfied.	0,4887			
	>10^5 copies/mL - <=10^6 copies/mL	91	12,4	38	41,8	53	58,2	6,00	3,00	9,00	10,00	8,00	13,00	123	16,4	42	34,1	81	65,9	6,00	4,00	8,00	13,00	8,00	19,00	0,1080	1,42	0,91	2,20	Convergence criterion (GCONV=1E-8) satisfied.				
	>10^6 copies/mL - <=10^7 copies/mL	119	16,2	54	45,4	65	54,6	8,00	5,00	9,00	11,00	10,00	14,00	125	16,7	56	44,8	69	55,2	8,00	6,00	11,00	14,00	12,00	17,00	0,2030	1,27	0,87	1,84	Convergence criterion (GCONV=1E-8) satisfied.				
	>10^7 copies/mL	363	49,3	167	46,0	196	54,0	7,00	6,00	8,00	10,00	9,00	12,00	346	46,3	142	41,0	204	59,0	9,00	8,00	10,00	13,00	12,00	16,00	0,0010	1,43	1,15	1,79	Convergence criterion (GCONV=1E-8) satisfied.				
	Unknown	2	0,3	2	100,0	0	0,0	18,00	18,00	22,00	20,00	18,00	22,00	4	0,5	2	50,0	2	50,0	8,00	8,00	13,00	10,50	8,00	13,00	0,0896	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.				
Country	USA	698	94,8	324	46,4	374	53,6	7,00	6,00	8,00	10,00	10,00	12,00	711	95,1	298	41,9	413	58,1	8,00	6,00	8,00	13,00	12,00	15,00	0,0003	1,32	1,13	1,55	Convergence criterion (GCONV=1E-8) satisfied.				
	MEX	38	5,2	0	0,0	38	100,0	NE	NE	NE	NE	NE	NE	37	4,9	0	0,0	37	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline serostatus	Negative	500	67,9	229	45,8	271	54,2	8,00	6,00	8,00	10,00	10,00	12,00	519	69,4	218	42,0	301	58,0	8,00	7,00	9,00	14,00	12,00	16,00	0,0005	1,37	1,14	1,65	Convergence criterion (GCONV=1E-8) satisfied.	0,6523			
	Positive	177	24,0	62	35,0	115	65,0	6,00	5,00	7,00	12,00	8,00	13,00	164	21,9	55	33,5	109	66,5	5,00	4,00	8,00	13,00	8,00	15,00	0,5188	1,12	0,78	1,62	Convergence criterion (GCONV=1E-8) satisfied.				
	Other	59	8,0	33	55,9	26	44,1	6,00	3,00	6,00	9,00	6,00	12,00	65	8,7	25	38,5	40	61,5	8,00	5,00	8,00	10,00	8,00	16,00	0,2730	1,32	0,79	2,23	Convergence criterion (GCONV=1E-8) satisfied.				

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-8-eff-tte-trtruh

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	748	748	377	354	334	318	300	281	261	229	199	180	162	147	138	120	110	90	78	72	67	59	57	55	49	48	47	45	42	25
Casirivimab/Imdevimab	736	736	367	344	316	291	270	247	227	185	152	128	112	99	89	76	64	58	56	51	46	40	37	33	30	24	24	23	17	9

Patients Censored

Placebo	0	371	373	374	374	376	376	379	379	380	380	380	380	381	382	382	382	383	384	384	385	386	386	386	387	387	388	390	403	424	
Casirivimab/Imdevimab	0	369	370	371	371	372	373	374	374	375	375	375	375	375	376	376	376	376	376	376	376	377	377	378	380	381	381	381	381	389	396

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-ttrtua.pdf

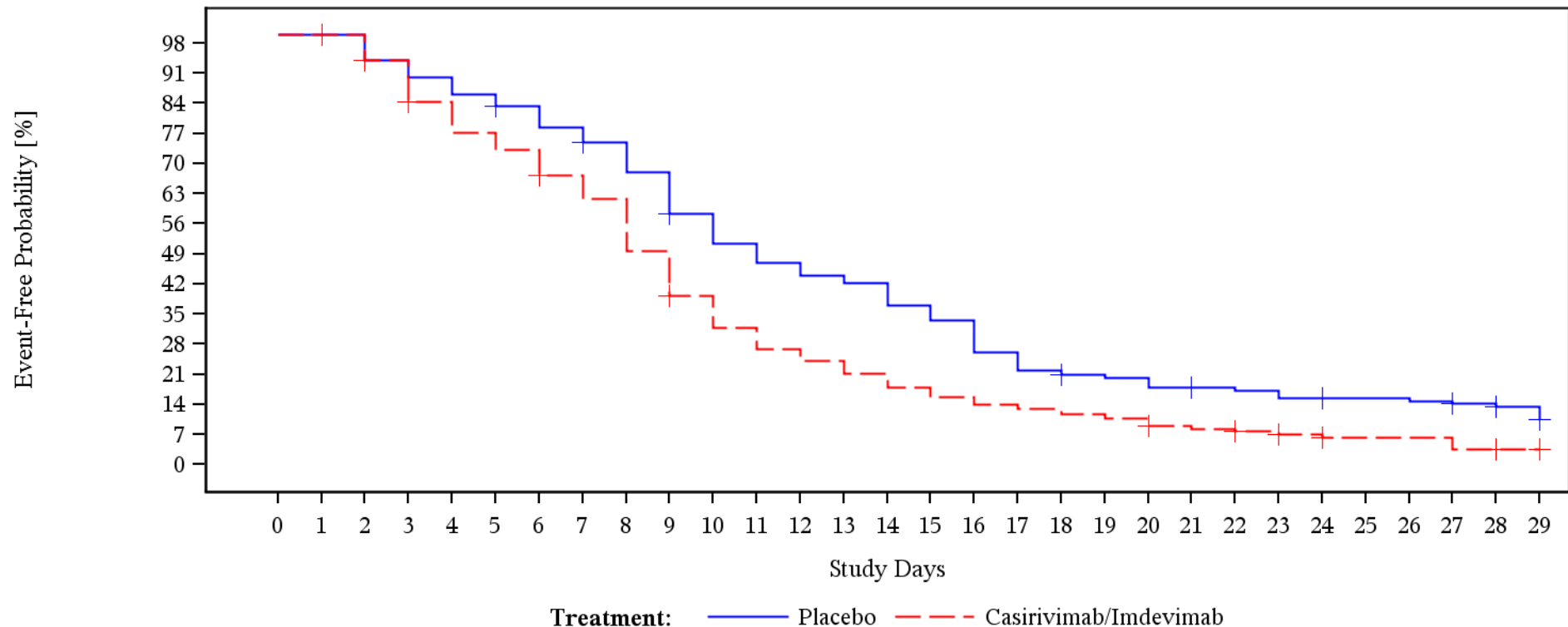
POPULATION: mFAS
 ENDPOINT: Time to return to usual activities
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo								Casirivimab/Imdevimab vs. Placebo								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event				log-rank	Hazard Ratio					
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	736	100,0	339	46,1	397	53,9	5,00	5,00	6,00	9,00	8,00	9,00	748	100,0	324	43,3	424	56,7	7,00	6,00	8,00	10,00	9,00	11,00	0,0001	1,33	1,14	1,55	Convergence criterion (GCCOV=1E-8) satisfied.

Stratification factor = Country
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-9-eff-tte-ttrtua

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

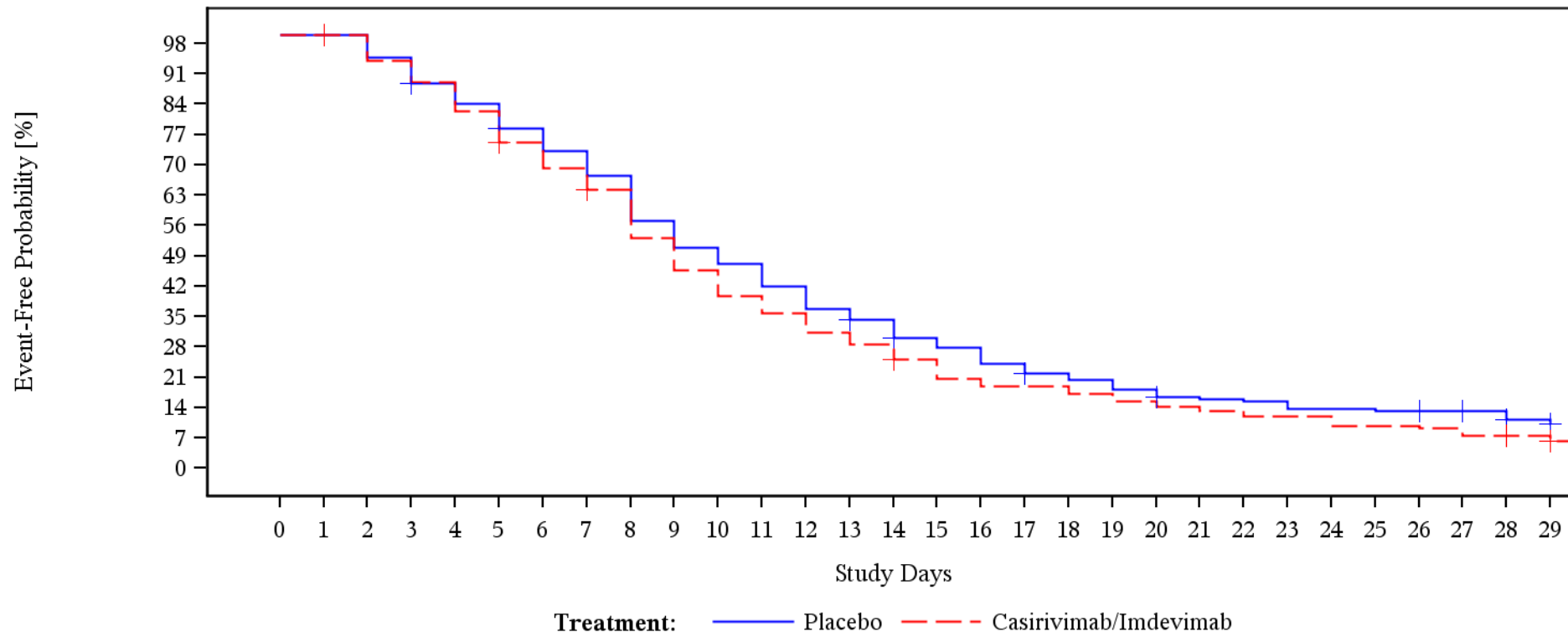
Placebo	352	352	182	169	162	155	149	140	131	119	101	89	81	76	73	64	58	45	38	35	34	30	29	28	25	24	24	23	21	14
Casirivimab/Imdevimab	364	364	185	173	154	141	134	122	112	90	70	57	48	43	38	32	28	25	23	21	19	15	14	12	9	7	7	7	4	2

Patients Censored

Placebo	0	170	172	172	172	173	173	176	176	177	177	177	177	177	177	177	177	177	178	178	178	179	179	179	180	180	180	181	187	198	
Casirivimab/Imdevimab	0	179	180	181	181	181	182	182	182	183	183	183	183	183	183	183	183	183	183	183	183	184	184	185	187	188	188	188	188	190	192

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

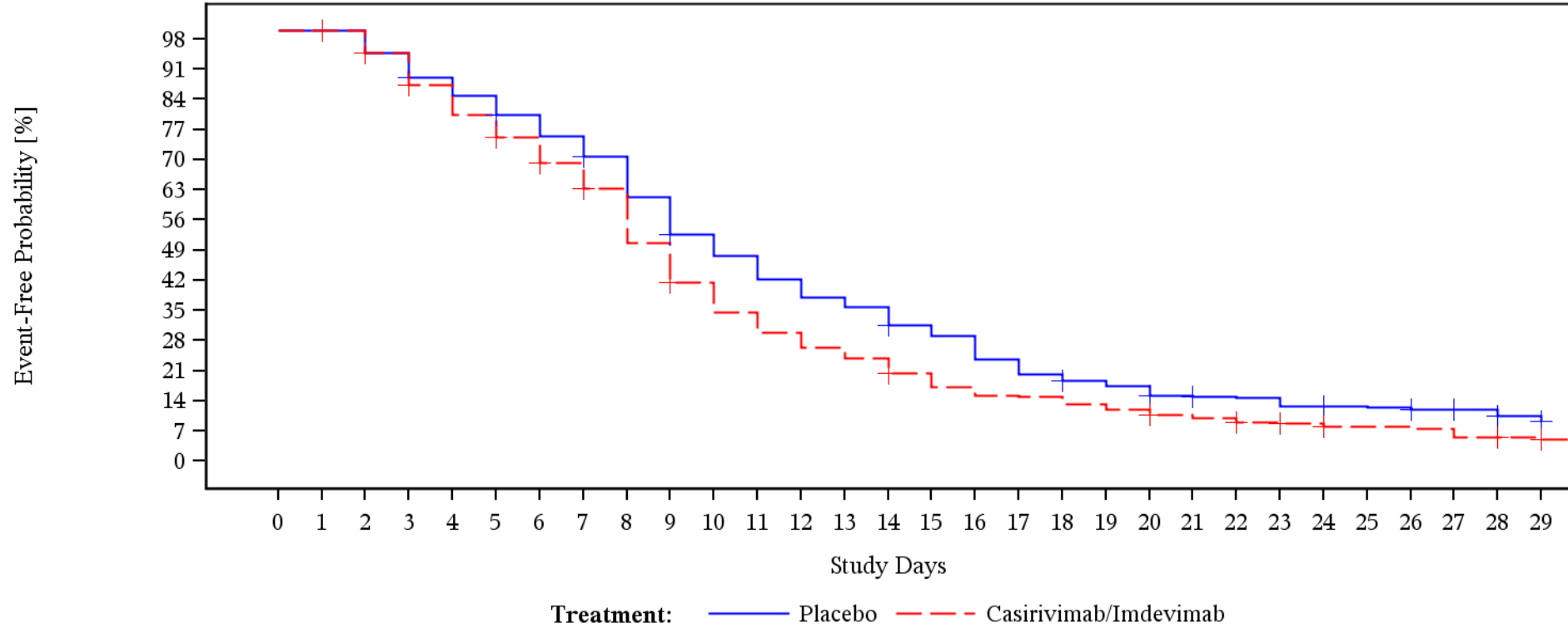
Placebo	396	396	195	185	172	163	151	141	130	110	98	91	81	71	65	56	52	45	40	37	33	29	28	27	24	24	23	22	21	11
Casirivimab/Imdevimab	372	372	182	171	162	150	136	125	115	95	82	71	64	56	51	44	36	33	33	30	27	25	23	21	21	17	17	16	13	7

Patients Censored

Placebo	0	201	201	202	202	203	203	203	203	203	203	203	203	204	205	205	205	206	206	206	207	207	207	207	207	207	207	207	207	208	209	216	226
Casirivimab/Imdevimab	0	190	190	190	190	191	191	192	192	192	192	192	192	192	193	193	193	193	193	193	193	193	193	193	193	193	193	193	193	193	199	204	

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

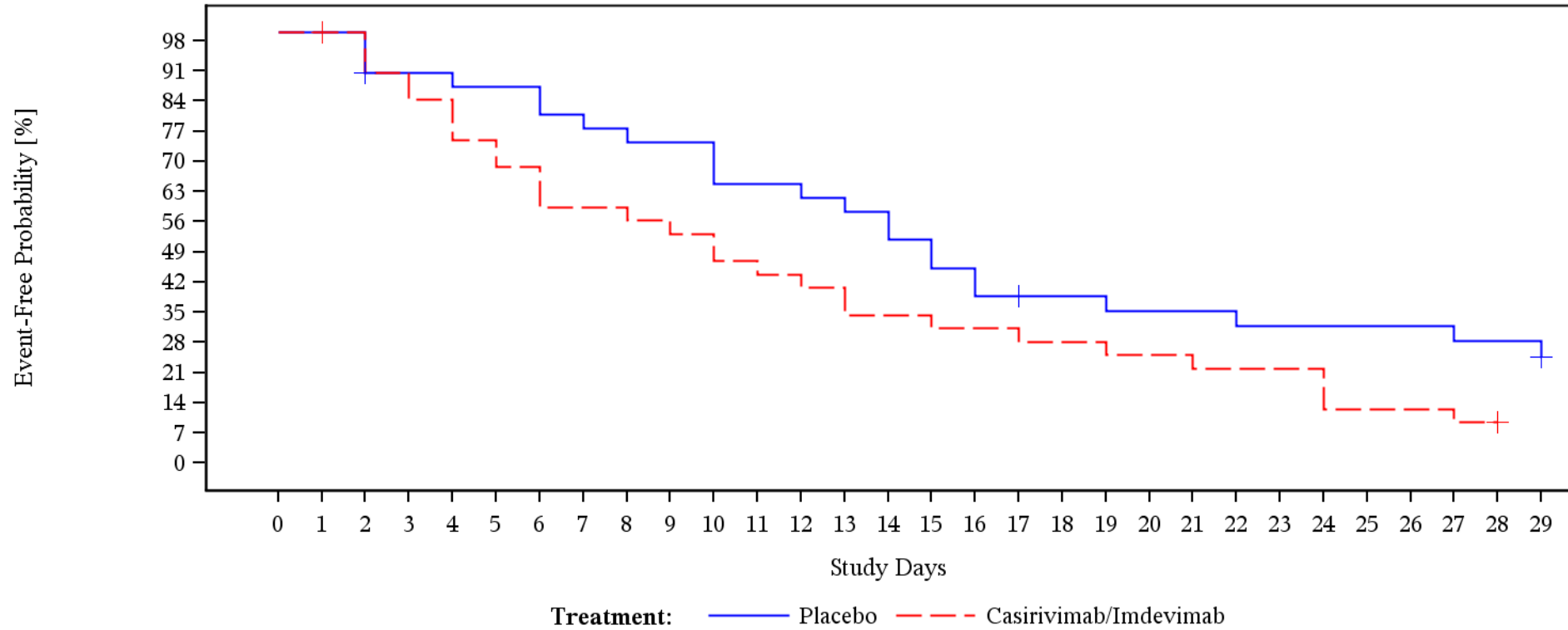
Placebo	660	660	339	320	300	286	270	253	234	203	173	157	139	125	118	103	95	77	66	60	56	48	46	45	39	38	37	35	33	16
Casirivimab/Imdevimab	643	643	324	306	281	259	241	221	201	161	131	109	94	83	75	63	53	47	46	41	37	32	30	26	23	20	20	19	14	9

Patients Censored

Placebo	0	321	322	323	323	324	324	327	327	328	328	328	328	328	329	329	329	329	330	330	331	332	332	332	333	333	334	336	349	363
Casirivimab/Imdevimab	0	319	320	321	321	322	323	324	324	325	325	325	325	326	326	326	326	326	326	326	327	327	328	330	331	331	331	331	336	343

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

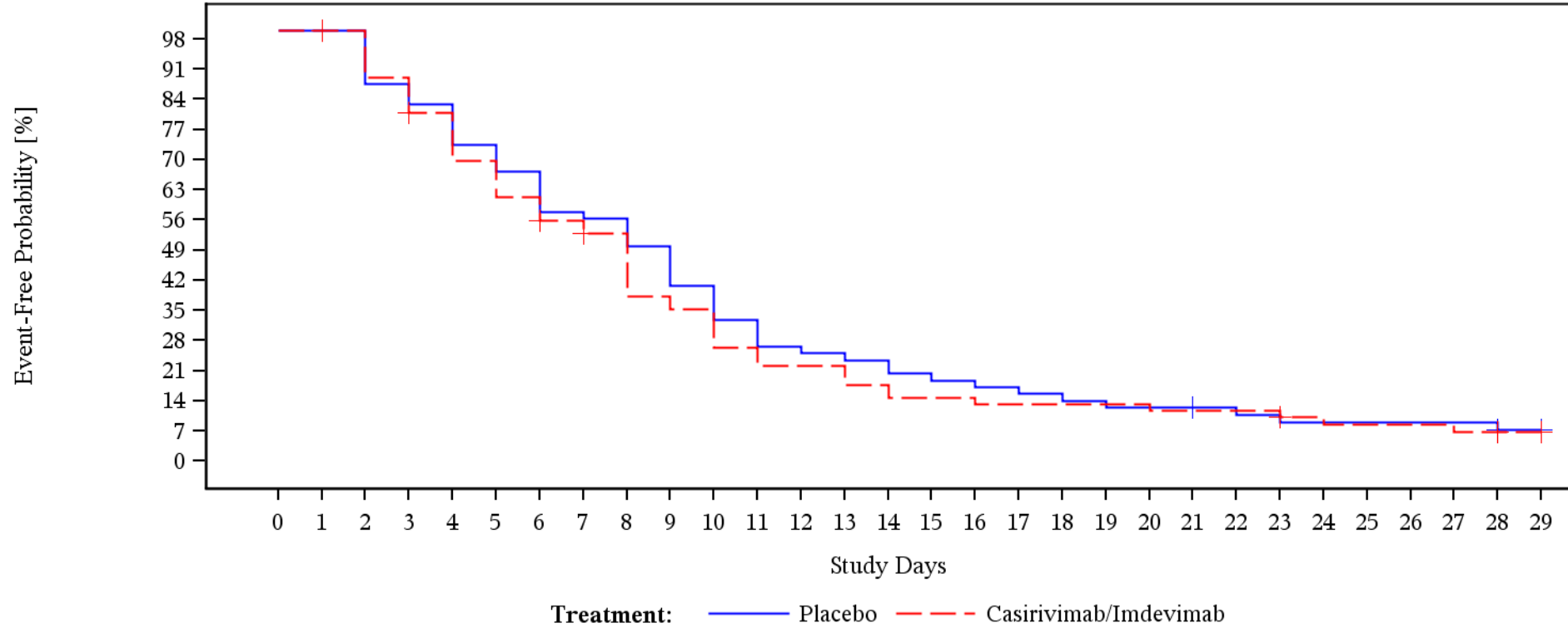
Placebo	68	68	32	28	28	27	27	25	24	23	23	20	19	18	16	14	12	11	11	10	10	10	9	9	9	9	9	8	8	
Casirivimab/Imdevimab	62	62	32	29	27	24	22	19	19	18	17	15	14	13	11	11	10	10	9	9	8	8	7	7	7	4	4	4	3	0

Patients Censored

Placebo	0	36	37	37	37	37	37	37	37	37	37	37	37	37	37	37	38	38	38	38	38	38	38	38	38	38	38	38	38	45
Casirivimab/Imdevimab	0	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	33	33

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

Placebo	150	150	64	56	53	47	43	37	36	32	26	21	17	16	15	13	12	11	10	9	8	8	7	6	5	5	5	5	5	3	
Casirivimab/Imdevimab	161	161	73	65	58	50	44	39	36	26	24	18	15	15	12	10	10	9	9	9	9	8	8	8	6	5	5	5	5	4	3

Patients Censored

Placebo	0	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	87	87	87	87	87	87	87	88	91		
Casirivimab/Imdevimab	0	88	88	89	89	89	90	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	91	92	92	92	92	92	92	93	96

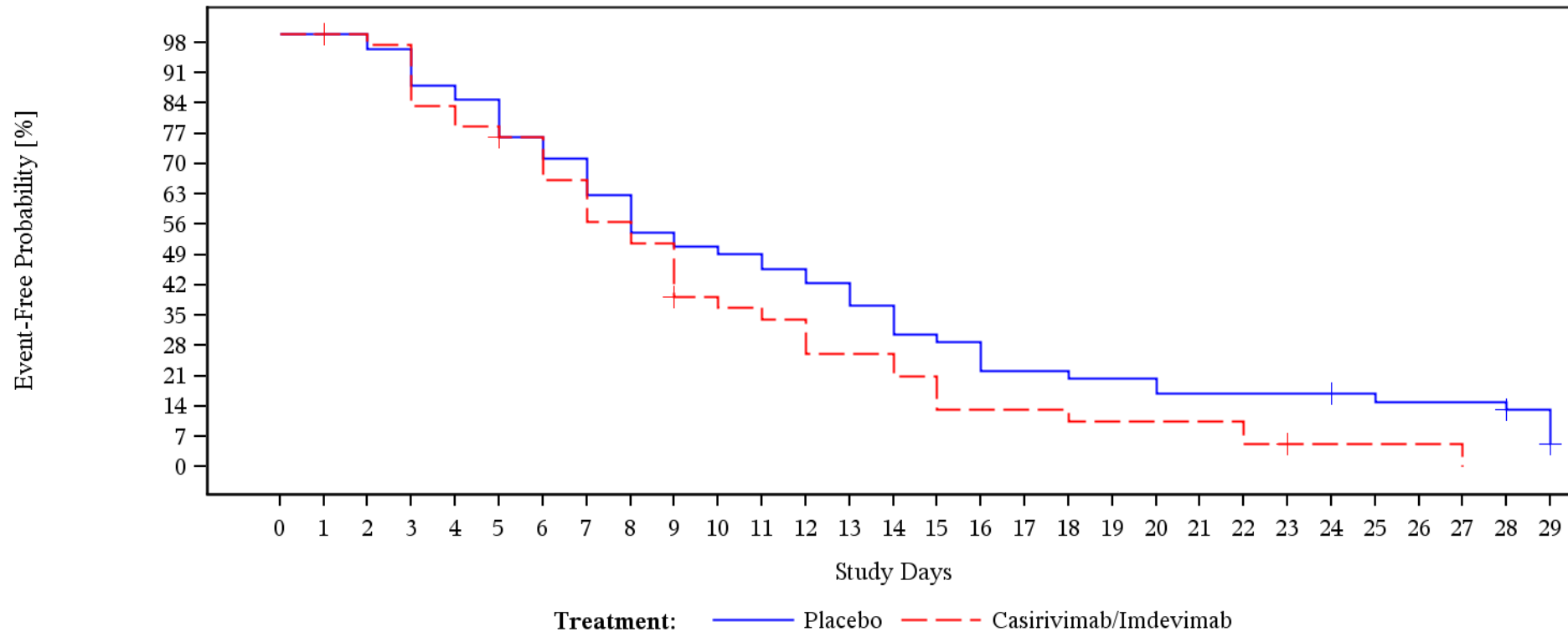
Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population

ENDPOINT: Return to usual activities: Time to 'Yes'

STUDYID: R10933-10987-COV-2067

Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

Placebo	123	123	59	57	52	50	45	42	37	32	30	29	27	25	22	18	17	13	13	12	12	10	10	10	10	9	8	8	8	5
Casirivimab/Imdevimab	91	91	42	41	35	33	31	27	23	21	15	14	13	10	10	8	5	5	5	4	4	4	4	2	1	1	1	1	0	0

Patients Censored

Placebo	0	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	64	65	65	65	65	67	69
Casirivimab/Imdevimab	0	49	49	49	49	50	50	50	50	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51	51

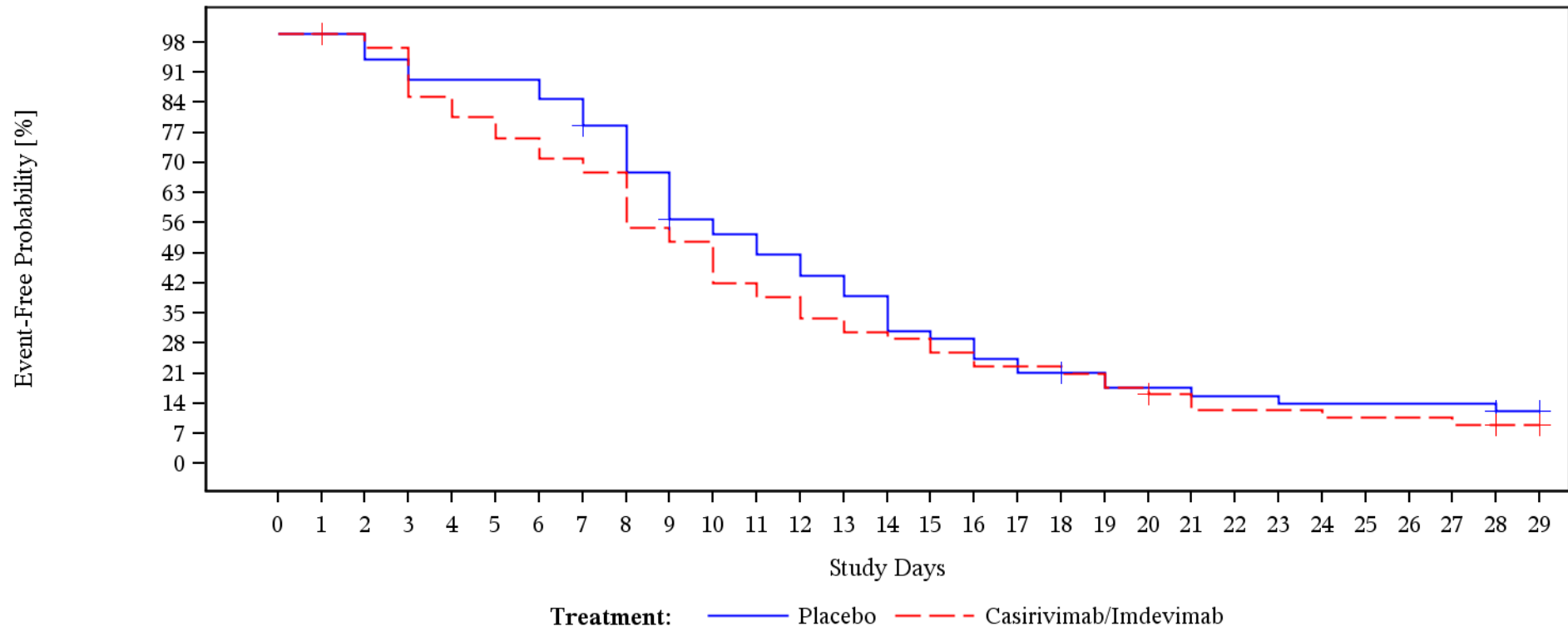
Showing data observed through Day 29

Clinical cutoff: 18FEB2021

Program: f-km-plot.sas

Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

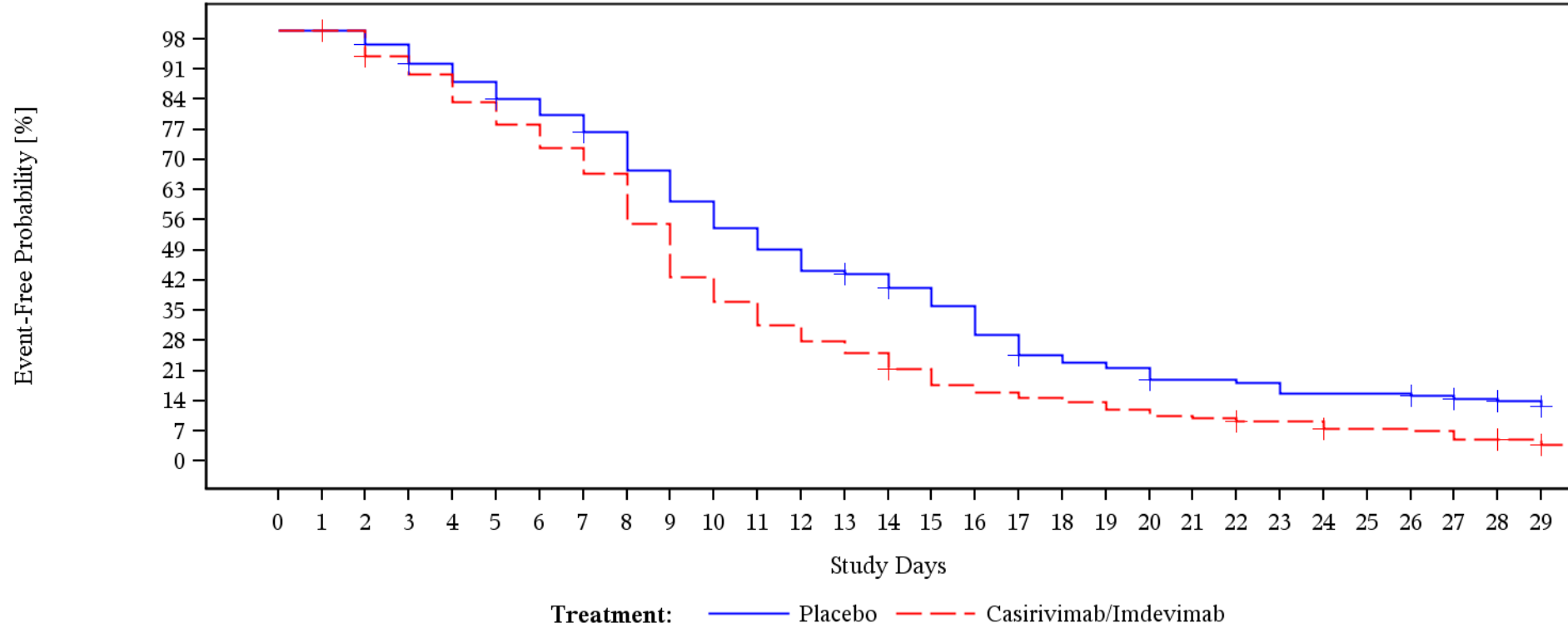
Placebo	125	125	66	62	59	59	59	56	50	43	35	33	30	27	24	19	18	15	13	12	10	10	9	9	8	8	8	8	8	4
Casirivimab/Imdevimab	119	119	62	60	53	50	47	44	42	34	32	26	24	21	19	18	16	14	14	13	11	9	7	7	7	6	6	6	5	2

Patients Censored

Placebo	0	59	59	59	59	59	59	61	61	62	62	62	62	62	62	62	62	62	63	63	63	63	63	63	63	63	63	63	66	70		
Casirivimab/Imdevimab	0	57	57	57	57	57	57	57	57	57	57	57	57	57	57	57	57	57	57	57	58	58	58	58	58	58	58	58	58	58	61	63

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

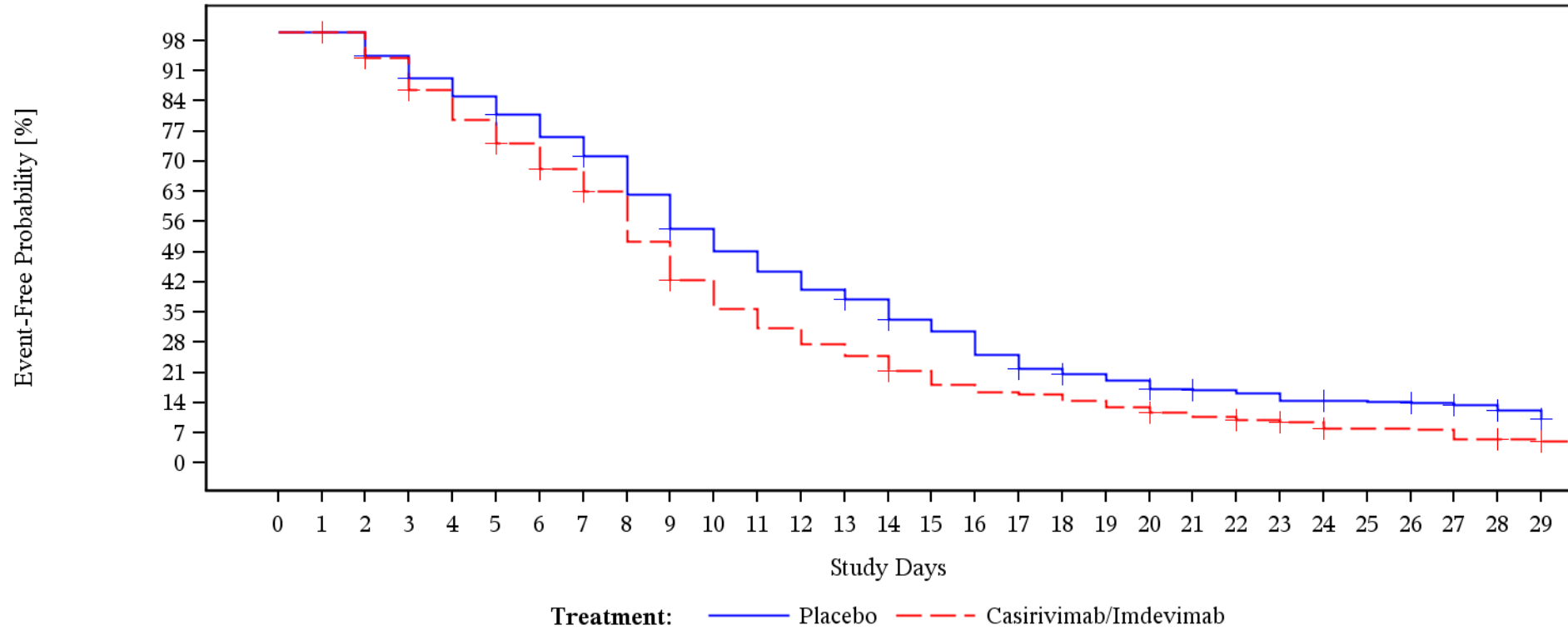
Placebo	346	346	186	178	169	161	152	145	137	121	108	97	88	79	77	70	63	51	42	39	37	31	31	30	26	26	26	24	21	13
Casirivimab/Imdevimab	363	363	188	176	168	156	146	136	125	103	80	69	59	52	47	39	32	29	27	25	22	19	18	16	16	12	12	11	8	4

Patients Censored

Placebo	0	160	162	163	163	165	165	166	166	166	166	166	166	167	168	168	168	169	169	169	170	170	170	170	170	170	171	173	180	192	
Casirivimab/Imdevimab	0	175	176	176	176	176	176	176	176	176	176	176	176	176	177	177	177	177	177	177	177	177	177	178	178	179	179	179	179	183	185

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

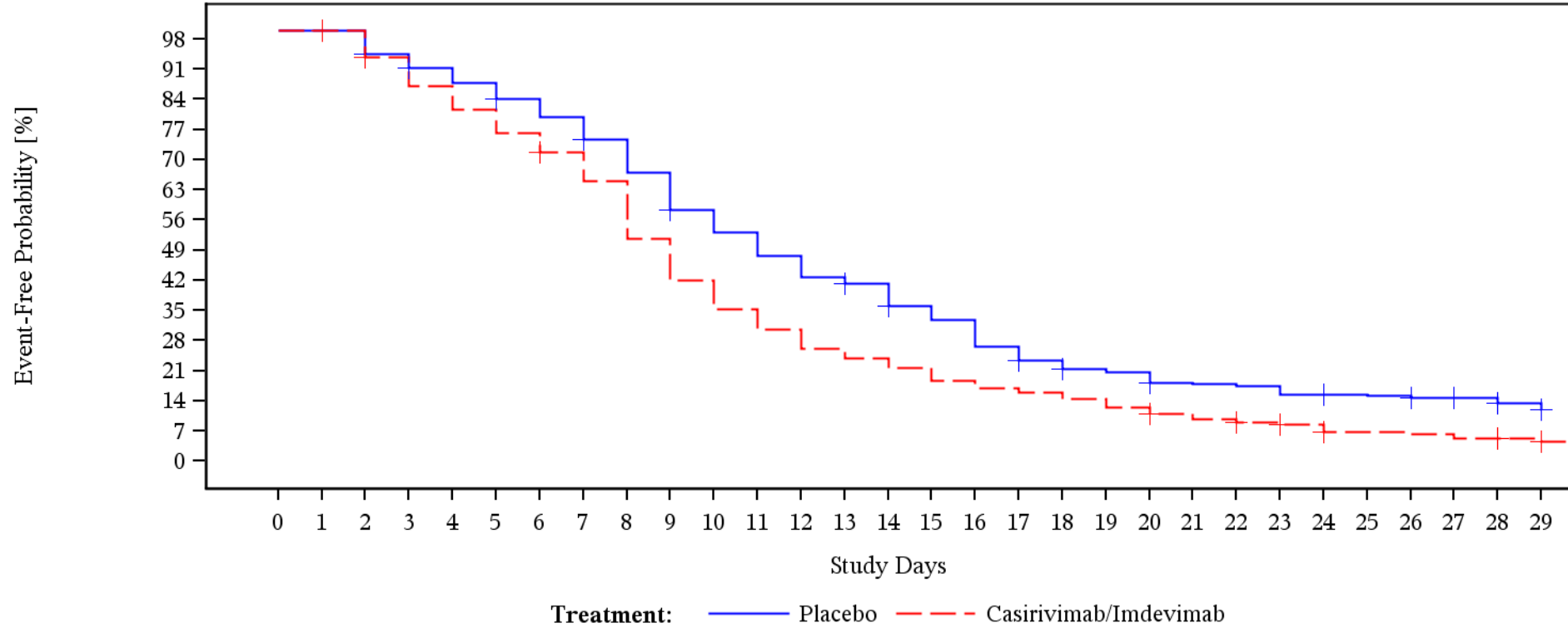
Placebo	711	711	377	354	334	318	300	281	261	229	199	180	162	147	138	120	110	90	78	72	67	59	57	55	49	48	47	45	42	25
Casirivimab/Imdevimab	698	698	367	344	316	291	270	247	227	185	152	128	112	99	89	76	64	58	56	51	46	40	37	33	30	24	24	23	17	9

Patients Censored

Placebo	0	334	336	337	337	339	339	342	342	343	343	343	343	344	345	345	345	346	347	347	348	349	349	349	350	350	351	353	366	387	
Casirivimab/Imdevimab	0	331	332	333	333	334	335	336	336	337	337	337	337	337	338	338	338	338	338	338	338	339	339	340	342	343	343	343	343	351	358

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

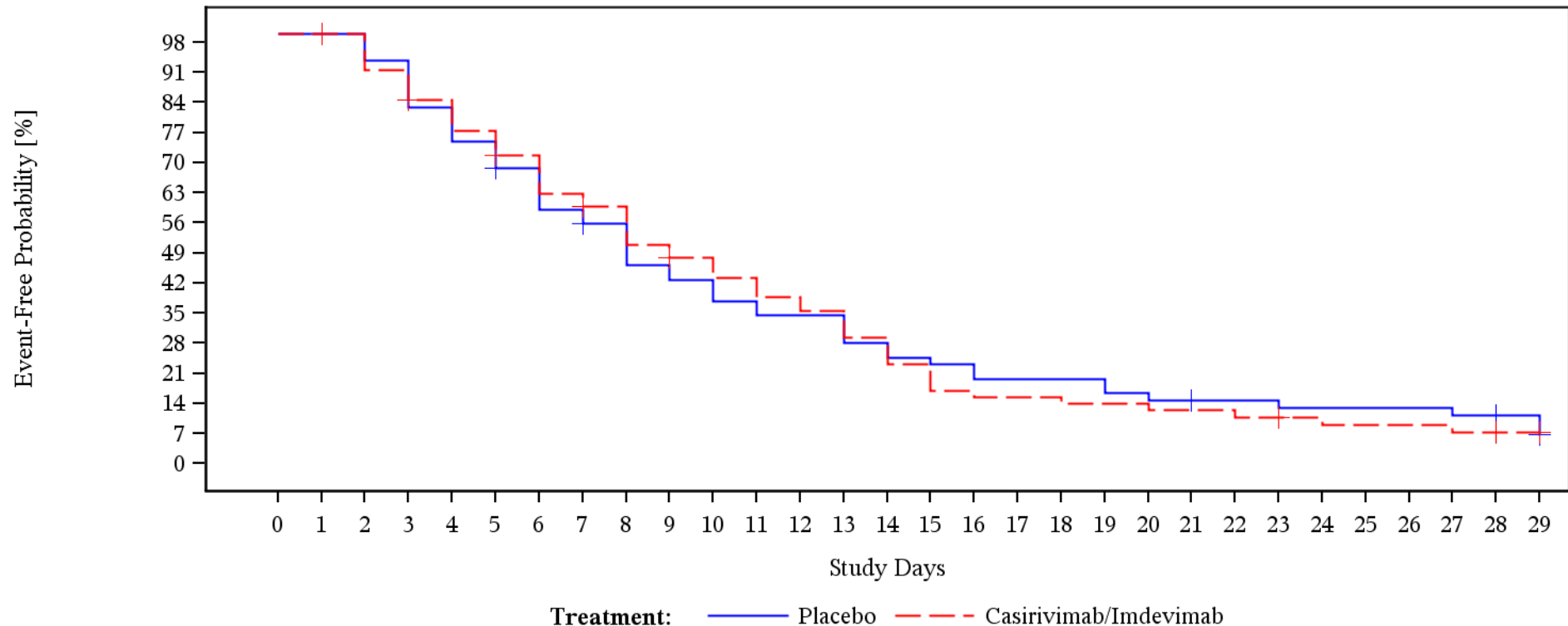
Placebo	519	519	280	263	253	243	232	220	204	183	158	144	129	116	111	96	87	71	61	55	53	46	45	44	39	38	37	35	33	20
Casirivimab/Imdevimab	500	500	258	241	224	210	196	183	166	132	107	90	78	67	61	55	48	43	41	37	32	27	24	21	19	14	14	13	11	7

Patients Censored

Placebo	0	239	241	242	242	243	243	245	245	246	246	246	246	247	248	248	248	249	250	250	251	251	251	251	252	252	253	255	265	283	
Casirivimab/Imdevimab	0	242	243	243	243	243	244	244	244	244	244	244	244	244	244	244	244	244	244	244	244	245	245	246	247	248	248	248	248	252	257

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

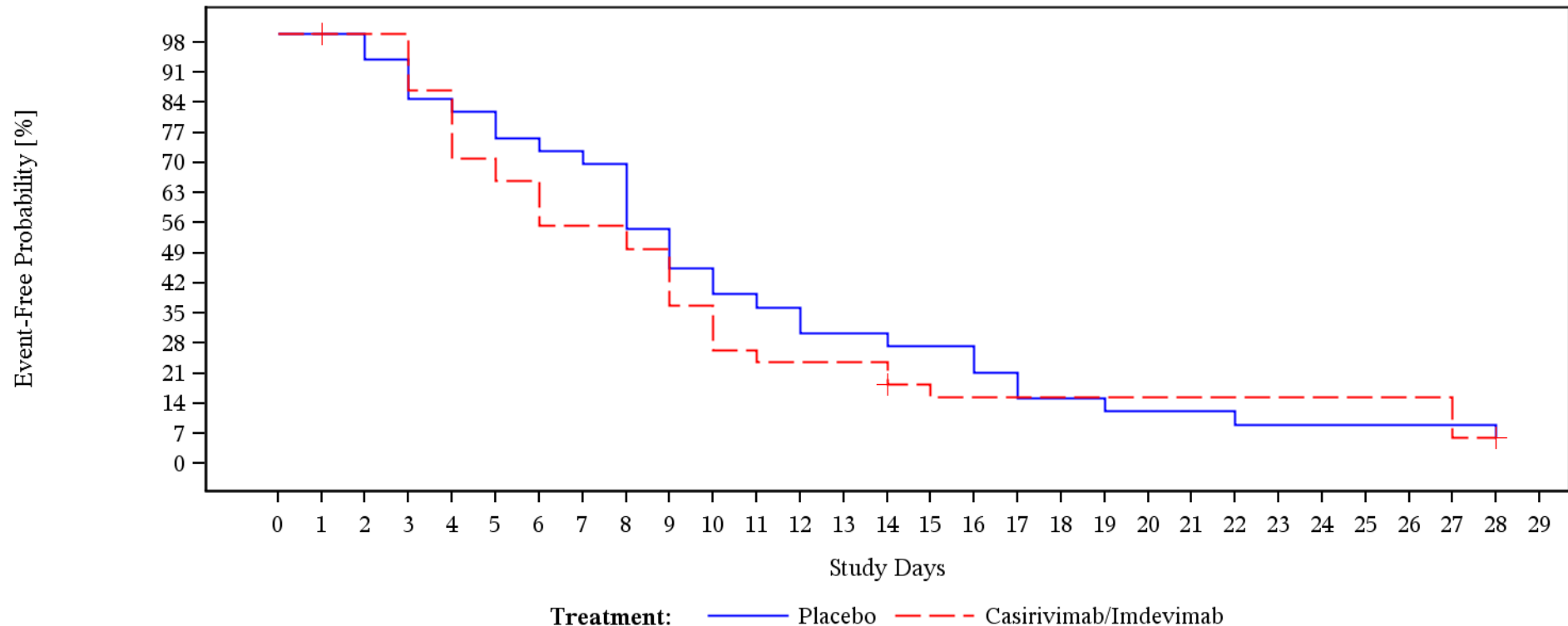
Placebo	164	164	64	60	53	48	43	37	34	28	26	23	21	21	17	15	14	12	12	12	10	9	8	8	7	7	7	7	6	5	
Casirivimab/Imdevimab	177	177	71	65	59	54	49	43	40	34	31	28	25	23	19	15	11	10	10	9	9	8	8	7	6	5	5	5	5	4	2

Patients Censored

Placebo	0	100	100	100	100	101	101	102	102	102	102	102	102	102	102	102	102	102	102	102	102	103	103	103	103	103	103	103	103	104	107	
Casirivimab/Imdevimab	0	106	106	107	107	108	108	109	109	110	110	110	110	110	110	110	110	110	110	110	110	110	110	110	111	111	111	111	111	111	113	115

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	65	65	33	31	28	27	25	24	23	18	15	13	12	10	10	9	9	7	5	5	4	4	4	3	3	3	3	3	3	0	
Casirivimab/Imdevimab	59	59	38	38	33	27	25	21	21	19	14	10	9	9	9	6	5	5	5	5	5	5	5	5	5	5	5	5	5	2	0

Patients Censored

Placebo	0	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	34	34	
Casirivimab/Imdevimab	0	21	21	21	21	21	21	21	21	21	21	21	21	21	21	22	22	22	22	22	22	22	22	22	22	22	22	22	22	24	24

Showing data observed through Day 29
 Clinical cutoff: 18FEB2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: mFAS
 ENDPOINT: Time to return to usual activities
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo						Casirivimab/Imdevimab vs. Placebo						Interaction Test										
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event							log-rank p-value	Hazard Ratio			p-value (likelihood ratio)					
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median			Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status				
All	n/a	736	100,0	339	46,1	397	53,9	5,00	5,00	6,00	9,00	8,00	9,00	748	100,0	324	43,3	424	56,7	7,00	6,00	8,00	10,00	9,00	11,00	0,0001	1,33	1,14	1,55	Convergence criterion (GCONV=1E-8) satisfied.						
Sex	Male	364	49,5	172	47,3	192	52,7	5,00	4,00	6,00	8,00	8,00	9,00	352	47,1	154	43,8	198	56,3	7,00	6,00	8,00	11,00	10,00	13,00	< 0,0001	1,56	1,25	1,94	Convergence criterion (GCONV=1E-8) satisfied.	0,0695					
	Female	372	50,5	167	44,9	205	55,1	6,00	5,00	7,00	9,00	8,00	10,00	396	52,9	170	42,9	226	57,1	6,00	5,00	7,00	10,00	8,00	11,00	0,1649	1,16	0,93	1,43	Convergence criterion (GCONV=1E-8) satisfied.						
Age	18-64	643	87,4	299	46,5	344	53,5	6,00	5,00	6,00	9,00	8,00	9,00	660	88,2	297	45,0	363	55,0	7,00	6,00	8,00	10,00	9,00	11,00	0,0009	1,29	1,10	1,52	Convergence criterion (GCONV=1E-8) satisfied.	0,5350					
	65-74	62	8,4	29	46,8	33	53,2	4,50	2,00	6,00	10,00	5,00	15,00	68	9,1	23	33,8	45	66,2	8,00	2,00	13,00	15,00	10,00	22,00	0,0565	1,68	0,96	2,93	Convergence criterion (GCONV=1E-8) satisfied.						
	>=75	31	4,2	11	35,5	20	64,5	3,00	2,00	9,00	9,00	2,00	14,00	20	2,7	4	20,0	16	80,0	5,00	4,00	29,00	14,00	4,00	29,00	0,1798	2,27	0,63	8,19	Convergence criterion (GCONV=1E-8) satisfied.						
Baseline viral load categories	<=10^5 copies/mL	161	21,9	65	40,4	96	59,6	4,00	3,00	5,00	8,00	5,00	8,00	150	20,1	59	39,3	91	60,7	4,00	3,00	6,00	8,50	6,00	10,00	0,5884	1,10	0,77	1,56	Convergence criterion (GCONV=1E-8) satisfied.	0,4524					
	>10^5 copies/mL - <=10^6 copies/mL	91	12,4	39	42,9	52	57,1	6,00	3,00	7,00	9,00	6,00	11,00	123	16,4	54	43,9	69	56,1	6,00	4,00	7,00	10,00	7,00	13,00	0,0848	1,42	0,93	2,17	Convergence criterion (GCONV=1E-8) satisfied.						
	>10^6 copies/mL - <=10^7 copies/mL	119	16,2	56	47,1	63	52,9	6,00	3,00	8,00	10,00	8,00	12,00	125	16,7	55	44,0	70	56,0	8,00	6,00	9,00	11,00	9,00	14,00	0,3499	1,19	0,82	1,72	Convergence criterion (GCONV=1E-8) satisfied.						
	>10^7 copies/mL	363	49,3	177	48,8	186	51,2	6,00	5,00	7,00	9,00	8,00	9,00	346	46,3	154	44,5	192	55,5	8,00	6,00	8,00	11,00	10,00	14,00	0,0001	1,49	1,20	1,86	Convergence criterion (GCONV=1E-8) satisfied.						
	Unknown	2	0,3	2	100,0	0	0,0	6,00	6,00	18,00	12,00	6,00	18,00	4	0,5	2	50,0	2	50,0	2,00	2,00	9,00	5,50	2,00	9,00	0,4328	0,39	0,03	4,44	Convergence criterion (GCONV=1E-8) satisfied.						
Country	USA	698	94,8	339	48,6	359	51,4	5,00	5,00	6,00	9,00	8,00	9,00	711	95,1	324	45,6	387	54,4	7,00	6,00	8,00	10,00	9,00	11,00	0,0001	1,33	1,14	1,55	Convergence criterion (GCONV=1E-8) satisfied.						
	MEX	38	5,2	0	0,0	38	100,0	NE	NE	NE	NE	NE	NE	37	4,9	0	0,0	37	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline serostatus	Negative	500	67,9	242	48,4	258	51,6	6,00	5,00	7,00	9,00	8,00	9,00	519	69,4	236	45,5	283	54,5	7,00	6,00	8,00	11,00	10,00	12,00	< 0,0001	1,44	1,21	1,73	Convergence criterion (GCONV=1E-8) satisfied.	0,2034					
	Positive	177	24,0	62	35,0	115	65,0	5,00	3,00	6,00	9,00	7,00	12,00	164	21,9	57	34,8	107	65,2	4,50	3,00	6,00	8,00	6,00	10,00	0,9351	1,01	0,71	1,46	Convergence criterion (GCONV=1E-8) satisfied.						
	Other	59	8,0	35	59,3	24	40,7	4,00	3,00	6,00	8,50	5,00	10,00	65	8,7	31	47,7	34	52,3	6,00	3,00	8,00	9,00	8,00	12,00	0,5991	1,13	0,70	1,84	Convergence criterion (GCONV=1E-8) satisfied.						

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-eff-tte.sas
 Output: t13-9-eff-tte-trttrua

Datenschnitt 18.02.2021 (DCO1)

Wirksamkeit

Ergänzende Dokumente

**Table 1.3: Number of patients for each subgroup and category per arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 748)	Casirivimab/Imdevimab (N = 736)
Sex (C) [n (%)]		
Male	352 (47.1)	364 (49.5)
Female	396 (52.9)	372 (50.5)
Age [n (%)]		
18-64	660 (88.2)	643 (87.4)
65-74	68 (9.1)	62 (8.4)
>=75	20 (2.7)	31 (4.2)
Baseline viral load categories [n (%)]		
<=10 ⁵ copies/mL	150 (20.1)	161 (21.9)
>10 ⁵ copies/mL - <=10 ⁶ copies/mL	123 (16.4)	91 (12.4)
>10 ⁶ copies/mL - <=10 ⁷ copies/mL	125 (16.7)	119 (16.2)
>10 ⁷ copies/mL	346 (46.3)	363 (49.3)
Unknown	4 (0.5)	2 (0.3)
Country [n (%)]		
United States	711 (95.1)	698 (94.8)
Mexico	37 (4.9)	38 (5.2)
Race/ethnicity [n (%)]		
White	611 (81.7)	595 (80.8)
Black or African American	38 (5.1)	38 (5.2)
Asian/American Indian Alaska Native/Native Hawaiian or other Pacific Islander	47 (6.3)	57 (7.7)
Unknown/Not Reported	52 (7.0)	46 (6.3)
Baseline SARS-CoV-2 Serology Status [n (%)]		
Negative	519 (69.4)	500 (67.9)
Positive	164 (21.9)	177 (24.0)
Other	65 (8.7)	59 (8.0)

POPULATION: mFAS
 ENDPOINT: --
 MODEL: --
 STUDY: R10933-10987-COV-2067
 Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm (mFAS Population)

Category	Center				Country				Geographical region ³			
	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷
Overall	69	100%	1484	100%	2	100%	1484	100%	2	100%	1484	100%
with <10 Patients per arm ¹	47	68.1%	290	19.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
with >=10 Patients per arm ²	22	31.9%	1194	80.5%	2	100%	1484	100%	2	100%	1484	100%

¹: '<10 patients category' if at least one treatment arm has <10 patients

²: '>=10 patients' category if all treatment arms have >=10 patients

³: Geographical regions: United States; Rest of the World

⁴: Number of centers, countries, or geographical regions

⁵: % of centers compared to overall number of centers, % of countries compared to overall number of countries, % of geographical regions compared to overall number of geographical regions

⁶: Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)

⁷: % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)

Clinical cut-off: 18Feb2021

Program: O:\Data\Development\MA\R10933-10987-restricted\R10933-10987-COV\MA-BT\COV2067DBL3_Cohort1\Analysis_MA\Programs\t3-center
 Output: O:\Data\Development\MA\R10933-10987-restricted\R10933-10987-COV\MA-BT\COV2067DBL3_Cohort1\Analysis_MA\Outputs\t3-center.xlsx

**Table 4: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 748)	Casirivimab/Imdevimab (N = 736)
Age (Years)		
n	748	736
Mean	47.10	47.62
SD	14.80	14.73
Median	48.0	48.5
Q1	35.0	37.0
Q3	57.000	57.500
Min	18.0	18.0
Max	89.0	90.0
Age Group (Years) [n (%)]		
18 - 44	300 (40.1)	303 (41.2)
45 - 64	360 (48.1)	340 (46.2)
65 - 84	85 (11.4)	90 (12.2)
>=85	3 (0.4)	3 (0.4)
Age Group 2 (Years) [n (%)]		
>=50	356 (47.6)	357 (48.5)
<50	392 (52.4)	379 (51.5)
Age Group 3 (Years) [n (%)]		
>=65	88 (11.8)	93 (12.6)
<65	660 (88.2)	643 (87.4)
Age Group 4 (Years) [n (%)]		
>=75	20 (2.7)	31 (4.2)
<75	728 (97.3)	705 (95.8)
Sex [n (%)]		
Male	352 (47.1)	364 (49.5)
Female	396 (52.9)	372 (50.5)
Ethnicity [n (%)]		
Hispanic or Latino	295 (39.4)	312 (42.4)
Not Hispanic or Latino	449 (60.0)	417 (56.7)
Not Reported	4 (0.5)	7 (1.0)

**Table 4: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 748)	Casirivimab/Imdevimab (N = 736)
Race [n (%)]		
White	611 (81.7)	595 (80.8)
Black or African American	38 (5.1)	38 (5.2)
Asian	36 (4.8)	38 (5.2)
American Indian or Alaska Native	10 (1.3)	17 (2.3)
Native Hawaiian or Other Pacific Islander	1 (0.1)	2 (0.3)
Unknown	37 (4.9)	36 (4.9)
Not Reported	15 (2.0)	10 (1.4)
Weight (kg)		
n	748	735
Missing	0	1
Mean	88.73	90.21
SD	21.80	23.28
Median	86.2	86.2
Q1	72.8	74.4
Q3	102.400	102.100
Min	43.1	45.1
Max	198.7	228.6
Height (cm)		
n	748	735
Missing	0	1
Mean	168.56	168.96
SD	11.29	11.20
Median	167.6	170.0
Q1	160.0	161.0
Q3	177.000	177.000
Min	120.0	123.0
Max	210.8	200.7

Table 5.1. Summary of Overall Patient Disposition
Phase 3 Cohort 1 with ≥ 1 Risk Factor for Severe COVID-19 post PA6
Modified Full Analysis Set

	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Randomized patients	748 (100%)	736 (100%)
Randomized patients but not treated	0	1 (0.1%)
Patients who completed the study	0	0
Patients ongoing in the study	738 (98.7%)	728 (98.9%)
Patients who discontinued the study	10 (1.3%)	8 (1.1%)
Reasons for study discontinuation		
Adverse Event	1 (0.1%)	0
Pregnancy	0	0
Lack of Efficacy	0	0
Physician Decision	0	0
Sponsor Request	0	0
Death	0	1 (0.1%)
Lost To Follow-Up	4 (0.5%)	1 (0.1%)
Subject Decision	5 (0.7%)	6 (0.8%)

Clinical cut-off: 18Feb2021

Table 5.2. Number of screened patients and reason for screening failure
All Screened Subjects

	Total (N=6716)
Number of Subjects Screened	6716
Randomized Subject	6411 (95.5%)
Subjects treated but not randomized	0
Subjects randomized but not treated	97 (1.4%)
Screen phase discontinuation	306 (4.6%)
Primary reasons for screen phase discontinuation	
Adverse Event	1 (<0.1%)
Lost To Follow-Up	1 (<0.1%)
Other	28 (0.4%)
Screen Failure	259 (3.9%)
Subject Decision	17 (0.3%)

Clinical cut-off: 18Feb2021

Percentage of each reason for screen failure is calculated based on number of screened patients.

**Table 2.2: Duration of Follow-up by domain and arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 748)	Casirivimab/ Imdevimab (N = 736)
Efficacy Follow-up (Days)		
Median	29.0	29.0
Safety 1 Follow-up (Days)		
Missing	0	1
Median	29.0	29.0
Safety 2 Follow-up (Days)		
Missing	0	1
Median	52.0	56.0

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant medication	480 (64.2%)	469 (63.7%)
ANALGESICS	169 (22.6%)	155 (21.1%)
ANILIDES	154 (20.6%)	135 (18.3%)
PARACETAMOL	141 (18.9%)	129 (17.5%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	8 (1.1%)	4 (0.5%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE HYDROCHLORIDE	7 (0.9%)	2 (0.3%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	2 (0.3%)
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRIN E	1 (0.1%)	1 (0.1%)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
CAFFEINE;PARACETAMOL	1 (0.1%)	0
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYL EPHRINE HYDROCHLORIDE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;P HENYLEPHRINE	1 (0.1%)	0
DOXYLAMINE SUCCINATE;PARACETAMOL IBUPROFEN;PARACETAMOL	1 (0.1%) 0	0 1 (0.1%)
PARACETAMOL;PHENYLEPHRINE	0	1 (0.1%)
OTHER ANALGESICS AND ANTIPYRETICS	8 (1.1%)	12 (1.6%)
GABAPENTIN	7 (0.9%)	11 (1.5%)
DULOXETINE	1 (0.1%)	0
PREGABALIN	0	1 (0.1%)
SALICYLIC ACID AND DERIVATIVES	5 (0.7%)	3 (0.4%)
ACETYLSALICYLIC ACID	5 (0.7%)	3 (0.4%)
OTHER ANTIMIGRAINE PREPARATIONS	0	7 (1.0%)
TOPIRAMATE	0	3 (0.4%)
AMITRIPTYLINE	0	2 (0.3%)
METOPROLOL	0	2 (0.3%)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	2 (0.3%)	4 (0.5%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
HYDROCODONE BITARTRATE;PARACETAMOL	1 (0.1%)	1 (0.1%)
CODEINE PHOSPHATE;PARACETAMOL	0	1 (0.1%)
CODEINE;PARACETAMOL	0	1 (0.1%)
HYDROCODONE;PARACETAMOL	1 (0.1%)	0
OXYCODONE HYDROCHLORIDE;PARACETAMOL	0	1 (0.1%)
SELECTIVE SEROTONIN (5HT1) AGONISTS	3 (0.4%)	3 (0.4%)
SUMATRIPTAN	2 (0.3%)	3 (0.4%)
SUMATRIPTAN SUCCINATE	1 (0.1%)	0
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS	0	3 (0.4%)
ERENUMAB	0	1 (0.1%)
FREMANEZUMAB	0	1 (0.1%)
GALCANEZUMAB	0	1 (0.1%)
NATURAL OPIUM ALKALOIDS	1 (0.1%)	2 (0.3%)
OXYCODONE	1 (0.1%)	1 (0.1%)
MORPHINE	0	1 (0.1%)
OTHER OPIOIDS	1 (0.1%)	2 (0.3%)
TRAMADOL	1 (0.1%)	2 (0.3%)
PYRAZOLONES	0	1 (0.1%)
METAMIZOLE	0	1 (0.1%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	142 (19.0%)	151 (20.5%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ACE INHIBITORS, PLAIN	74 (9.9%)	75 (10.2%)
LISINOPRIL	64 (8.6%)	55 (7.5%)
ENALAPRIL	6 (0.8%)	7 (1.0%)
BENAZEPRIL	1 (0.1%)	6 (0.8%)
CAPTOPRIL	0	5 (0.7%)
RAMIPRIL	1 (0.1%)	2 (0.3%)
BENAZEPRIL HYDROCHLORIDE	1 (0.1%)	0
FOSINOPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	63 (8.4%)	69 (9.4%)
LOSARTAN	48 (6.4%)	45 (6.1%)
VALSARTAN	7 (0.9%)	6 (0.8%)
OLMESARTAN	3 (0.4%)	4 (0.5%)
IRBESARTAN	2 (0.3%)	4 (0.5%)
TELMISARTAN	2 (0.3%)	4 (0.5%)
OLMESARTAN MEDOXOMIL	2 (0.3%)	3 (0.4%)
LOSARTAN POTASSIUM	0	2 (0.3%)
AZILSARTAN KAMEDOXOMIL	0	1 (0.1%)
ACE INHIBITORS AND DIURETICS	2 (0.3%)	3 (0.4%)
HYDROCHLOROTHIAZIDE;LISINOPRIL	2 (0.3%)	3 (0.4%)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	2 (0.3%)	1 (0.1%)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	2 (0.3%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	0	2 (0.3%)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	0	1 (0.1%)
HYDROCHLOROTHIAZIDE;VALSARTAN	0	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	0	1 (0.1%)
AMLODIPINE BESILATE;VALSARTAN	0	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS	1 (0.1%)	0
SACUBITRIL VALSARTAN SODIUM HYDRATE	1 (0.1%)	0
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	92 (12.3%)	79 (10.7%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	62 (8.3%)	57 (7.7%)
SALBUTAMOL	55 (7.4%)	50 (6.8%)
SALBUTAMOL SULFATE	6 (0.8%)	4 (0.5%)
FORMOTEROL	1 (0.1%)	1 (0.1%)
LEVOSALBUTAMOL	1 (0.1%)	1 (0.1%)
LEVOSALBUTAMOL HYDROCHLORIDE	1 (0.1%)	0
LEVOSALBUTAMOL TARTRATE	0	1 (0.1%)
PROCATEROL HYDROCHLORIDE	0	1 (0.1%)
SALMETEROL	0	1 (0.1%)
LEUKOTRIENE RECEPTOR ANTAGONISTS	12 (1.6%)	18 (2.4%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
MONTELUKAST	6 (0.8%)	10 (1.4%)
MONTELUKAST SODIUM	6 (0.8%)	8 (1.1%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	20 (2.7%)	9 (1.2%)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	9 (1.2%)	6 (0.8%)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	6 (0.8%)	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE	5 (0.7%)	1 (0.1%)
FLUTICASONE PROPIONATE;SALMETEROL	0	1 (0.1%)
ANTICHOLINERGICS	7 (0.9%)	6 (0.8%)
IPRATROPIUM BROMIDE	4 (0.5%)	1 (0.1%)
IPRATROPIUM	1 (0.1%)	3 (0.4%)
TIOTROPIUM BROMIDE	1 (0.1%)	1 (0.1%)
GLYCOPYRRONIUM	0	1 (0.1%)
UMECLIDINIUM BROMIDE	1 (0.1%)	0
GLUCOCORTICOIDS	8 (1.1%)	5 (0.7%)
FLUTICASONE	4 (0.5%)	0
FLUTICASONE PROPIONATE	2 (0.3%)	2 (0.3%)
BUDESONIDE	1 (0.1%)	1 (0.1%)
BECLOMETASONE DIPROPIONATE	0	1 (0.1%)
CICLESONIDE	0	1 (0.1%)
MOMETASONE FUROATE	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	5 (0.7%)	4 (0.5%)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	3 (0.4%)	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	0	1 (0.1%)
IPRATROPIUM BROMIDE;SALBUTAMOL	0	1 (0.1%)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	1 (0.1%)	0
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	1 (0.1%)	0
UMECLIDINIUM;VILANTEROL	0	1 (0.1%)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0	1 (0.1%)
OMALIZUMAB	0	1 (0.1%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	77 (10.3%)	77 (10.5%)
PROPIONIC ACID DERIVATIVES	65 (8.7%)	66 (9.0%)
IBUPROFEN	58 (7.8%)	57 (7.7%)
NAPROXEN	3 (0.4%)	6 (0.8%)
NAPROXEN SODIUM	5 (0.7%)	2 (0.3%)
HYDROCODONE BITARTRATE;IBUPROFEN	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OXICAMS	7 (0.9%)	3 (0.4%)
MELOXICAM	7 (0.9%)	3 (0.4%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	4 (0.5%)	5 (0.7%)
DICLOFENAC	2 (0.3%)	1 (0.1%)
DICLOFENAC POTASSIUM	1 (0.1%)	1 (0.1%)
DICLOFENAC SODIUM	1 (0.1%)	1 (0.1%)
ETODOLAC	0	2 (0.3%)
KETOROLAC TROMETHAMINE	1 (0.1%)	0
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	1 (0.1%)	5 (0.7%)
BENZYDAMINE	1 (0.1%)	1 (0.1%)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	0	2 (0.3%)
BENZYDAMINE HYDROCHLORIDE	0	1 (0.1%)
GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	0	1 (0.1%)
COXIBS	2 (0.3%)	0
CELECOXIB	2 (0.3%)	0
LIPID MODIFYING AGENTS	68 (9.1%)	81 (11.0%)
HMG COA REDUCTASE INHIBITORS	62 (8.3%)	76 (10.3%)
ATORVASTATIN	22 (2.9%)	37 (5.0%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
SIMVASTATIN	12 (1.6%)	13 (1.8%)
ROSUVASTATIN	7 (0.9%)	10 (1.4%)
ROSUVASTATIN CALCIUM	5 (0.7%)	10 (1.4%)
ATORVASTATIN CALCIUM	7 (0.9%)	4 (0.5%)
PRAVASTATIN	4 (0.5%)	3 (0.4%)
LOVASTATIN	2 (0.3%)	1 (0.1%)
PITAVASTATIN CALCIUM	2 (0.3%)	0
PRAVASTATIN SODIUM	1 (0.1%)	0
OTHER LIPID MODIFYING AGENTS	6 (0.8%)	12 (1.6%)
FISH OIL	5 (0.7%)	3 (0.4%)
EZETIMIBE	1 (0.1%)	4 (0.5%)
EICOSAPENTAENOIC ACID ETHYL ESTER	0	3 (0.4%)
ALIROCUMAB	1 (0.1%)	0
OMEGA-3 NOS	0	1 (0.1%)
OMEGA-3-ACID ETHYL ESTER	0	1 (0.1%)
SITOSTEROL	0	1 (0.1%)
FIBRATES	2 (0.3%)	3 (0.4%)
FENOFIBRATE	2 (0.3%)	2 (0.3%)
GEMFIBROZIL	0	1 (0.1%)
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	1 (0.1%)	1 (0.1%)
CARTHAMUS TINCTORIUS OIL	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
MONASCUS PURPUREUS	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS IN COMBINATION WITH OTHER LIPID MODIFYING AGENTS	2 (0.3%)	0
EZETIMIBE;SIMVASTATIN	2 (0.3%)	0
ANTITHROMBOTIC AGENTS	71 (9.5%)	62 (8.4%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	50 (6.7%)	52 (7.1%)
ACETYLSALICYLIC ACID	48 (6.4%)	46 (6.3%)
CLOPIDOGREL	2 (0.3%)	6 (0.8%)
CLOPIDOGREL BISULFATE	0	4 (0.5%)
PRASUGREL	0	2 (0.3%)
EPOPROSTENOL	1 (0.1%)	0
PRASUGREL HYDROCHLORIDE	0	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	16 (2.1%)	9 (1.2%)
APIXABAN	12 (1.6%)	6 (0.8%)
RIVAROXABAN	4 (0.5%)	3 (0.4%)
HEPARIN GROUP	12 (1.6%)	3 (0.4%)
ENOXAPARIN	6 (0.8%)	1 (0.1%)
ENOXAPARIN SODIUM	5 (0.7%)	2 (0.3%)
HEPARIN SODIUM	1 (0.1%)	0
VITAMIN K ANTAGONISTS	0	1 (0.1%)
WARFARIN	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
VITAMINS	63 (8.4%)	51 (6.9%)
VITAMIN D AND ANALOGUES	36 (4.8%)	29 (3.9%)
VITAMIN D NOS	23 (3.1%)	20 (2.7%)
COLECALCIFEROL	13 (1.7%)	9 (1.2%)
ERGOCALCIFEROL	1 (0.1%)	0
ASCORBIC ACID (VITAMIN C), PLAIN	33 (4.4%)	27 (3.7%)
ASCORBIC ACID	33 (4.4%)	27 (3.7%)
MULTIVITAMINS, PLAIN	13 (1.7%)	16 (2.2%)
VITAMINS NOS	12 (1.6%)	16 (2.2%)
ASCORBIC ACID;CALCIUM PANTOTHENATE;COLECALCIFEROL;CYANOCOBALAMIN ;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1 (0.1%)	0
OTHER PLAIN VITAMIN PREPARATIONS	2 (0.3%)	3 (0.4%)
BIOTIN	1 (0.1%)	1 (0.1%)
NICOTINAMIDE	1 (0.1%)	0
TOCOPHERYL ACETATE	0	1 (0.1%)
VITAMIN E NOS	0	1 (0.1%)
MULTIVITAMINS WITH MINERALS	1 (0.1%)	3 (0.4%)
MINERALS NOS;VITAMINS NOS	1 (0.1%)	2 (0.3%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID;	0	1 (0.1%)
COMBINATIONS OF VITAMINS	3 (0.4%)	0
ASCORBIC ACID;VITAMIN D NOS	1 (0.1%)	0
COLECALCIFEROL;MENAQUINONE-7	1 (0.1%)	0
VITAMINS NOS	1 (0.1%)	0
VITAMIN B-COMPLEX, PLAIN	2 (0.3%)	0
VITAMIN B COMPLEX	2 (0.3%)	0
VITAMINS, OTHER COMBINATIONS	2 (0.3%)	0
ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM;MANGANES E;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	2 (0.3%)	0
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.1%)	0
MINERALS NOS;VITAMINS NOS	1 (0.1%)	0
VITAMIN A AND D IN COMBINATION	1 (0.1%)	0
COD-LIVER OIL	1 (0.1%)	0
VITAMIN A, PLAIN	1 (0.1%)	0
VITAMIN A NOS	1 (0.1%)	0
VITAMIN B-COMPLEX WITH VITAMIN C	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0	1 (0.1%)
VITAMIN B1, PLAIN	1 (0.1%)	0
THIAMINE HYDROCHLORIDE	1 (0.1%)	0
VITAMINS WITH MINERALS	1 (0.1%)	0
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID;	1 (0.1%)	0
DRUGS USED IN DIABETES	56 (7.5%)	56 (7.6%)
BIGUANIDES	40 (5.3%)	42 (5.7%)
METFORMIN	37 (4.9%)	42 (5.7%)
METFORMIN HYDROCHLORIDE	3 (0.4%)	0
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	13 (1.7%)	6 (0.8%)
INSULIN LISPRO	7 (0.9%)	3 (0.4%)
INSULIN ASPART	4 (0.5%)	2 (0.3%)
INSULIN	1 (0.1%)	1 (0.1%)
INSULIN HUMAN	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	9 (1.2%)	7 (1.0%)
INSULIN GLARGINE	6 (0.8%)	6 (0.8%)
INSULIN DEGLUDEC	1 (0.1%)	1 (0.1%)
INSULIN DETEMIR	2 (0.3%)	0
SULFONYLUREAS	9 (1.2%)	6 (0.8%)
GLIPIZIDE	7 (0.9%)	5 (0.7%)
GLIMEPIRIDE	2 (0.3%)	1 (0.1%)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	4 (0.5%)	7 (1.0%)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	2 (0.3%)	4 (0.5%)
EMPAGLIFLOZIN	2 (0.3%)	1 (0.1%)
CANAGLIFLOZIN	0	2 (0.3%)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES	7 (0.9%)	3 (0.4%)
DULAGLUTIDE	3 (0.4%)	1 (0.1%)
SEMAGLUTIDE	2 (0.3%)	2 (0.3%)
EXENATIDE	1 (0.1%)	0
LIRAGLUTIDE	1 (0.1%)	0
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	1 (0.1%)	4 (0.5%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	0	2 (0.3%)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	1 (0.1%)	1 (0.1%)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	0	1 (0.1%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	3 (0.4%)	2 (0.3%)
SITAGLIPTIN	2 (0.3%)	2 (0.3%)
LINAGLIPTIN	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	2 (0.3%)	1 (0.1%)
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	2 (0.3%)	1 (0.1%)
ALPHA GLUCOSIDASE INHIBITORS	1 (0.1%)	0
ACARBOSE	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	0	1 (0.1%)
INSULIN ASPART;INSULIN ASPART PROTAMINE	0	1 (0.1%)
THIAZOLIDINEDIONES	1 (0.1%)	0
PIOGLITAZONE HYDROCHLORIDE	1 (0.1%)	0
ANTIBACTERIALS FOR SYSTEMIC USE	53 (7.1%)	45 (6.1%)
MACROLIDES	32 (4.3%)	29 (3.9%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
AZITHROMYCIN	30 (4.0%)	28 (3.8%)
CLARITHROMYCIN	1 (0.1%)	1 (0.1%)
AZITHROMYCIN DIHYDRATE	1 (0.1%)	0
THIRD-GENERATION CEPHALOSPORINS	10 (1.3%)	9 (1.2%)
CEFTRIAZONE	8 (1.1%)	4 (0.5%)
CEFDINIR	3 (0.4%)	5 (0.7%)
TETRACYCLINES	7 (0.9%)	3 (0.4%)
DOXYCYCLINE	6 (0.8%)	3 (0.4%)
MINOCYCLINE	1 (0.1%)	0
FLUOROQUINOLONES	3 (0.4%)	6 (0.8%)
LEVOFLOXACIN	2 (0.3%)	6 (0.8%)
CIPROFLOXACIN	1 (0.1%)	0
PENICILLINS WITH EXTENDED SPECTRUM	1 (0.1%)	3 (0.4%)
AMOXICILLIN	1 (0.1%)	2 (0.3%)
AMPICILLIN	0	1 (0.1%)
ANTIBACTERIALS FOR SYSTEMIC USE	1 (0.1%)	2 (0.3%)
PENICILLIN NOS	0	2 (0.3%)
BROAD SPECTRUM ANTIBIOTICS	1 (0.1%)	0
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	3 (0.4%)	0
AMOXICILLIN;CLAVULANIC ACID	2 (0.3%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	1 (0.1%)	0
CARBAPENEMS	1 (0.1%)	0
MEROPENEM	1 (0.1%)	0
FOURTH-GENERATION CEPHALOSPORINS	0	1 (0.1%)
CEFEPIME	0	1 (0.1%)
GLYCOPEPTIDE ANTIBACTERIALS	1 (0.1%)	0
VANCOMYCIN	1 (0.1%)	0
INTERMEDIATE-ACTING SULFONAMIDES	1 (0.1%)	0
SULFAMETHOXAZOLE	1 (0.1%)	0
LINCOSAMIDES	0	1 (0.1%)
LINCOMYCIN	0	1 (0.1%)
NITROFURAN DERIVATIVES	0	1 (0.1%)
NITROFURANTOIN	0	1 (0.1%)
TRIMETHOPRIM AND DERIVATIVES	1 (0.1%)	0
TRIMETHOPRIM	1 (0.1%)	0
BETA BLOCKING AGENTS	44 (5.9%)	44 (6.0%)
BETA BLOCKING AGENTS, SELECTIVE	28 (3.7%)	37 (5.0%)
METOPROLOL	12 (1.6%)	20 (2.7%)
ATENOLOL	11 (1.5%)	7 (1.0%)
NEBIVOLOL HYDROCHLORIDE	1 (0.1%)	5 (0.7%)
METOPROLOL TARTRATE	2 (0.3%)	3 (0.4%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
METOPROLOL SUCCINATE	1 (0.1%)	2 (0.3%)
BISOPROLOL	1 (0.1%)	0
ALPHA AND BETA BLOCKING AGENTS	14 (1.9%)	6 (0.8%)
CARVEDILOL	12 (1.6%)	6 (0.8%)
LABETALOL	2 (0.3%)	0
LABETALOL HYDROCHLORIDE	1 (0.1%)	0
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0.1%)	2 (0.3%)
SOTALOL	0	2 (0.3%)
PROPRANOLOL	1 (0.1%)	0
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	1 (0.1%)	0
BISOPROLOL;HYDROCHLOROTHIAZIDE	1 (0.1%)	0
CALCIUM CHANNEL BLOCKERS	36 (4.8%)	47 (6.4%)
DIHYDROPYRIDINE DERIVATIVES	33 (4.4%)	44 (6.0%)
AMLODIPINE	26 (3.5%)	37 (5.0%)
AMLODIPINE BESILATE	4 (0.5%)	4 (0.5%)
NIFEDIPINE	3 (0.4%)	2 (0.3%)
FELODIPINE	0	1 (0.1%)
BENZOTHIAZEPINE DERIVATIVES	2 (0.3%)	3 (0.4%)
DILTIAZEM	2 (0.3%)	2 (0.3%)
DILTIAZEM HYDROCHLORIDE	0	1 (0.1%)
PHENYLALKYLAMINE DERIVATIVES	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
VERAPAMIL	1 (0.1%)	0
DIURETICS	44 (5.9%)	37 (5.0%)
THIAZIDES, PLAIN	29 (3.9%)	28 (3.8%)
HYDROCHLOROTHIAZIDE	29 (3.9%)	28 (3.8%)
SULFONAMIDES, PLAIN	10 (1.3%)	7 (1.0%)
FUROSEMIDE	4 (0.5%)	5 (0.7%)
CHLORTALIDONE	3 (0.4%)	1 (0.1%)
BUMETANIDE	1 (0.1%)	1 (0.1%)
INDAPAMIDE	2 (0.3%)	0
TORASEMIDE	1 (0.1%)	0
ALDOSTERONE ANTAGONISTS	1 (0.1%)	2 (0.3%)
SPIRONOLACTONE	1 (0.1%)	2 (0.3%)
OTHER POTASSIUM-SPARING AGENTS	1 (0.1%)	2 (0.3%)
TRIAMTERENE	1 (0.1%)	2 (0.3%)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	2 (0.3%)	0
HYDROCHLOROTHIAZIDE;TRIAMTERENE	2 (0.3%)	0
DIURETICS	1 (0.1%)	0
ISOSORBIDE	1 (0.1%)	0
DRUGS FOR ACID RELATED DISORDERS	43 (5.7%)	34 (4.6%)
PROTON PUMP INHIBITORS	39 (5.2%)	32 (4.3%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OMEPRAZOLE	25 (3.3%)	13 (1.8%)
PANTOPRAZOLE	8 (1.1%)	10 (1.4%)
ESOMEPRAZOLE	4 (0.5%)	5 (0.7%)
LANSOPRAZOLE	2 (0.3%)	1 (0.1%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0	2 (0.3%)
DEXLANSOPRAZOLE	0	1 (0.1%)
H2-RECEPTOR ANTAGONISTS	5 (0.7%)	1 (0.1%)
FAMOTIDINE	5 (0.7%)	1 (0.1%)
ALUMINIUM COMPOUNDS	1 (0.1%)	0
ALUMINIUM HYDROXIDE	1 (0.1%)	0
ANTACIDS WITH SODIUM BICARBONATE	0	1 (0.1%)
SODIUM BICARBONATE	0	1 (0.1%)
CALCIUM COMPOUNDS	1 (0.1%)	0
CALCIUM CARBONATE	1 (0.1%)	0
PSYCHOANALEPTICS	33 (4.4%)	40 (5.4%)
OTHER ANTIDEPRESSANTS	12 (1.6%)	20 (2.7%)
TRAZODONE	3 (0.4%)	6 (0.8%)
LAMOTRIGINE	5 (0.7%)	2 (0.3%)
BUPROPION	0	5 (0.7%)
BUPROPION HYDROCHLORIDE	3 (0.4%)	2 (0.3%)
DULOXETINE	2 (0.3%)	2 (0.3%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
VENLAFAXINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
DULOXETINE HYDROCHLORIDE	1 (0.1%)	0
MIRTAZAPINE	0	1 (0.1%)
VENLAFAXINE	0	1 (0.1%)
VILAZODONE HYDROCHLORIDE	1 (0.1%)	0
VORTIOXETINE HYDROBROMIDE	0	1 (0.1%)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	11 (1.5%)	13 (1.8%)
CITALOPRAM	2 (0.3%)	5 (0.7%)
SERTRALINE	3 (0.4%)	3 (0.4%)
ESCITALOPRAM OXALATE	3 (0.4%)	1 (0.1%)
FLUOXETINE HYDROCHLORIDE	0	2 (0.3%)
SERTRALINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
CITALOPRAM HYDROBROMIDE	1 (0.1%)	0
ESCITALOPRAM	0	1 (0.1%)
FLUOXETINE	1 (0.1%)	0
CENTRALLY ACTING SYMPATHOMIMETICS	11 (1.5%)	7 (1.0%)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	7 (0.9%)	4 (0.5%)
LISDEXAMFETAMINE MESILATE	1 (0.1%)	2 (0.3%)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ATOMOXETINE	1 (0.1%)	0
LISDEXAMFETAMINE	1 (0.1%)	0
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	2 (0.3%)	3 (0.4%)
AMITRIPTYLINE	2 (0.3%)	2 (0.3%)
DOXEPIN	0	1 (0.1%)
ANTICHOLINESTERASES	0	2 (0.3%)
DONEPEZIL	0	2 (0.3%)
XANTHINE DERIVATIVES	0	2 (0.3%)
CAFFEINE	0	2 (0.3%)
OTHER ANTI-DEMENTIA DRUGS	0	1 (0.1%)
MEMANTINE	0	1 (0.1%)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	1 (0.1%)	0
GUANFACINE	1 (0.1%)	0
PSYCHOLEPTICS	29 (3.9%)	34 (4.6%)
BENZODIAZEPINE DERIVATIVES	8 (1.1%)	14 (1.9%)
CLONAZEPAM	3 (0.4%)	4 (0.5%)
LORAZEPAM	2 (0.3%)	5 (0.7%)
ALPRAZOLAM	3 (0.4%)	2 (0.3%)
TEMAZEPAM	1 (0.1%)	2 (0.3%)
DIAZEPAM	0	1 (0.1%)
OTHER ANXIOLYTICS	7 (0.9%)	14 (1.9%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ESCITALOPRAM	1 (0.1%)	6 (0.8%)
ESCITALOPRAM OXALATE	1 (0.1%)	2 (0.3%)
SERTRALINE	2 (0.3%)	1 (0.1%)
PAROXETINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
AMITRIPTYLINE	0	1 (0.1%)
DULOXETINE HYDROCHLORIDE	0	1 (0.1%)
FLUOXETINE	0	1 (0.1%)
LAVANDULA ANGUSTIFOLIA ESSENTIAL OIL	1 (0.1%)	0
PAROXETINE	1 (0.1%)	0
PROPRANOLOL	0	1 (0.1%)
SERTRALINE HYDROCHLORIDE	0	1 (0.1%)
MELATONIN RECEPTOR AGONISTS	9 (1.2%)	4 (0.5%)
MELATONIN	9 (1.2%)	4 (0.5%)
BENZODIAZEPINE RELATED DRUGS	2 (0.3%)	3 (0.4%)
ZOLPIDEM TARTRATE	1 (0.1%)	2 (0.3%)
ESZOPICLONE	1 (0.1%)	0
ZOLPIDEM	0	1 (0.1%)
OTHER ANTIPSYCHOTICS	2 (0.3%)	3 (0.4%)
ARIPIRAZOLE	1 (0.1%)	3 (0.4%)
VALPROATE SEMISODIUM	1 (0.1%)	0
AZASPIRODECANEDIONE DERIVATIVES	4 (0.5%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
BUSPIRONE	3 (0.4%)	0
BUSPIRONE HYDROCHLORIDE	1 (0.1%)	0
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	3 (0.4%)	0
QUETIAPINE FUMARATE	2 (0.3%)	0
OLANZAPINE	1 (0.1%)	0
DIPHENYLMETHANE DERIVATIVES	1 (0.1%)	2 (0.3%)
HYDROXYZINE	1 (0.1%)	1 (0.1%)
HYDROXYZINE EMBONATE	0	1 (0.1%)
OTHER HYPNOTICS AND SEDATIVES	1 (0.1%)	1 (0.1%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (0.1%)
DOXEPIN	1 (0.1%)	0
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	2 (0.3%)	0
PROCHLORPERAZINE	2 (0.3%)	0
BARBITURATES, PLAIN	0	1 (0.1%)
BUTALBITAL	0	1 (0.1%)
THYROID THERAPY	28 (3.7%)	34 (4.6%)
THYROID HORMONES	28 (3.7%)	31 (4.2%)
LEVOTHYROXINE	17 (2.3%)	22 (3.0%)
LEVOTHYROXINE SODIUM	11 (1.5%)	9 (1.2%)
LIOthyronine SODIUM	1 (0.1%)	0
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0	3 (0.4%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
THIAMAZOLE	0	3 (0.4%)
MINERAL SUPPLEMENTS	28 (3.7%)	27 (3.7%)
ZINC	20 (2.7%)	21 (2.9%)
ZINC	18 (2.4%)	20 (2.7%)
ZINC SULFATE	1 (0.1%)	1 (0.1%)
ZINC ACETATE;ZINC GLUCONATE	1 (0.1%)	0
MAGNESIUM	5 (0.7%)	5 (0.7%)
MAGNESIUM	4 (0.5%)	4 (0.5%)
MAGNESIUM CHLORIDE	0	1 (0.1%)
MAGNESIUM CITRATE	0	1 (0.1%)
MAGNESIUM MALATE	0	1 (0.1%)
MAGNESIUM OXIDE	1 (0.1%)	0
CALCIUM	2 (0.3%)	4 (0.5%)
CALCIUM	2 (0.3%)	3 (0.4%)
CALCIUM CARBONATE	0	1 (0.1%)
POTASSIUM	3 (0.4%)	3 (0.4%)
POTASSIUM	2 (0.3%)	1 (0.1%)
POTASSIUM CHLORIDE	1 (0.1%)	2 (0.3%)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	2 (0.3%)	0
CALCIUM CITRATE;COLECALCIFEROL	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1%)	0
SODIUM	2 (0.3%)	0
SODIUM	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
OTHER MINERAL PRODUCTS	1 (0.1%)	0
STRONTIUM	1 (0.1%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	38 (5.1%)	14 (1.9%)
GLUCOCORTICIDS	38 (5.1%)	14 (1.9%)
DEXAMETHASONE	26 (3.5%)	6 (0.8%)
PREDNISONE	7 (0.9%)	4 (0.5%)
METHYLPREDNISOLONE	3 (0.4%)	3 (0.4%)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	0	2 (0.3%)
BECLOMETASONE	0	1 (0.1%)
CORTISONE	1 (0.1%)	0
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (0.1%)	0
COUGH AND COLD PREPARATIONS	32 (4.3%)	18 (2.4%)
EXPECTORANTS	13 (1.7%)	7 (1.0%)
GUAIFENESIN	13 (1.7%)	7 (1.0%)
OPIUM ALKALOIDS AND DERIVATIVES	7 (0.9%)	6 (0.8%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DEXTROMETHORPHAN	3 (0.4%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (0.1%)	2 (0.3%)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
BROMPHENIRAMINE;HYDROCODONE;PSEUDOEPHEDRIN E	1 (0.1%)	0
CHLORPHENAMINE;HYDROCODONE BITARTRATE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PROMETHAZINE HYDROCHLORIDE	0	1 (0.1%)
HOMATROPINE;HYDROCODONE	1 (0.1%)	0
OPIUM DERIVATIVES AND EXPECTORANTS	3 (0.4%)	5 (0.7%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	1 (0.1%)	2 (0.3%)
CODEINE PHOSPHATE;GUAIFENESIN	1 (0.1%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	0	2 (0.3%)
DEXTROMETHORPHAN;GUAIFENESIN	1 (0.1%)	0
OTHER COUGH SUPPRESSANTS	7 (0.9%)	1 (0.1%)
BENZONATATE	7 (0.9%)	1 (0.1%)
MUCOLYTICS	2 (0.3%)	2 (0.3%)
ACETYLCYSTEINE	1 (0.1%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
BROMHEXINE	1 (0.1%)	1 (0.1%)
COUGH AND COLD PREPARATIONS	2 (0.3%)	1 (0.1%)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL	0	1 (0.1%)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
EUCALYPTUS GLOBULUS OIL;MENTHOL	1 (0.1%)	0
ANTIHISTAMINES FOR SYSTEMIC USE	22 (2.9%)	22 (3.0%)
PIPERAZINE DERIVATIVES	10 (1.3%)	11 (1.5%)
CETIRIZINE	6 (0.8%)	5 (0.7%)
CETIRIZINE HYDROCHLORIDE	4 (0.5%)	6 (0.8%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	7 (0.9%)	4 (0.5%)
LORATADINE	3 (0.4%)	4 (0.5%)
FEXOFENADINE HYDROCHLORIDE	2 (0.3%)	0
EPINASTINE	1 (0.1%)	0
QUERCETIN	1 (0.1%)	0
AMINOALKYL ETHERS	4 (0.5%)	5 (0.7%)
DOXYLAMINE SUCCINATE	1 (0.1%)	3 (0.4%)
DIPHENHYDRAMINE	1 (0.1%)	1 (0.1%)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (0.3%)	0
CARBINOXAMINE	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
PHENOTHIAZINE DERIVATIVES	3 (0.4%)	1 (0.1%)
PROMETHAZINE	3 (0.4%)	1 (0.1%)
SUBSTITUTED ALKYLAMINES	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE	1 (0.1%)	0
DEXBROMPHENIRAMINE	0	1 (0.1%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	21 (2.8%)	20 (2.7%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	10 (1.3%)	8 (1.1%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	5 (0.7%)	1 (0.1%)
ETHINYLESTRADIOL;NORGESTIMATE	2 (0.3%)	3 (0.4%)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	0	3 (0.4%)
DROSPIRENONE;ETHINYLESTRADIOL	1 (0.1%)	1 (0.1%)
DROSPIRENONE;ETHINYLESTRADIOL BETADEx CLATHRATE	1 (0.1%)	0
ETHINYLESTRADIOL;LEVONORGESTREL	1 (0.1%)	0
-OXOANDROSTEN (4) DERIVATIVES	4 (0.5%)	5 (0.7%)
TESTOSTERONE	3 (0.4%)	3 (0.4%)
TESTOSTERONE CIPIONATE	1 (0.1%)	1 (0.1%)
TESTOSTERONE ENANTHATE	0	1 (0.1%)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	3 (0.4%)	5 (0.7%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ESTRADIOL	3 (0.4%)	4 (0.5%)
ETHINYLESTRADIOL	0	1 (0.1%)
PROGESTOGENS	0	4 (0.5%)
ETONOGESTREL	0	2 (0.3%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.1%)
NORETHISTERONE	0	1 (0.1%)
PREGNEN (4) DERIVATIVES	2 (0.3%)	0
PROGESTERONE	2 (0.3%)	0
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS	1 (0.1%)	1 (0.1%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	1 (0.1%)	1 (0.1%)
EMERGENCY CONTRACEPTIVES	1 (0.1%)	0
LEVONORGESTREL	1 (0.1%)	0
ESTROGENS, COMBINATIONS WITH OTHER DRUGS	1 (0.1%)	0
BAZEDOXIFENE;ESTROGENS CONJUGATED	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	23 (3.1%)	12 (1.6%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	19 (2.5%)	6 (0.8%)
REMDESIVIR	13 (1.7%)	2 (0.3%)
VALACICLOVIR	3 (0.4%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
VALACICLOVIR HYDROCHLORIDE	2 (0.3%)	2 (0.3%)
ACICLOVIR	0	1 (0.1%)
VALGANCICLOVIR HYDROCHLORIDE	1 (0.1%)	0
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	3 (0.4%)	6 (0.8%)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFIVIR ALAFENAMIDE FUMARATE	2 (0.3%)	3 (0.4%)
EMTRICITABINE;TENOFIVIR DISOPROXIL FUMARATE	1 (0.1%)	2 (0.3%)
DOLUTEGRAVIR;LAMIVUDINE	0	1 (0.1%)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3%)	0
LY 3819253	2 (0.3%)	0
NEURAMINIDASE INHIBITORS	0	1 (0.1%)
OSELTAMIVIR	0	1 (0.1%)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
ABACAVIR	0	1 (0.1%)
OTHER ANTIVIRALS	1 (0.1%)	0
THYMALFASIN	1 (0.1%)	0
NASAL PREPARATIONS	10 (1.3%)	14 (1.9%)
CORTICOSTEROIDS	5 (0.7%)	9 (1.2%)
FLUTICASONE PROPIONATE	3 (0.4%)	5 (0.7%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
FLUTICASONE	2 (0.3%)	2 (0.3%)
BUDESONIDE	0	1 (0.1%)
TRIAMCINOLONE ACETONIDE	0	1 (0.1%)
SYMPATHOMIMETICS	3 (0.4%)	2 (0.3%)
BROMPHENIRAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
PHENYLEPHRINE	1 (0.1%)	0
PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.1%)
PSEUDOEPHEDRINE	0	1 (0.1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
SYMPATHOMIMETICS, PLAIN	2 (0.3%)	1 (0.1%)
OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.1%)
PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
TETRYZOLINE	1 (0.1%)	0
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	1 (0.1%)	1 (0.1%)
AZELASTINE	1 (0.1%)	1 (0.1%)
OTHER NASAL PREPARATIONS	0	2 (0.3%)
IPRATROPIUM BROMIDE	0	1 (0.1%)
SODIUM CHLORIDE;XYLITOL	0	1 (0.1%)
ALL OTHER THERAPEUTIC PRODUCTS	17 (2.3%)	5 (0.7%)
MEDICAL GASES	16 (2.1%)	4 (0.5%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OXYGEN	16 (2.1%)	4 (0.5%)
OTHER THERAPEUTIC PRODUCTS	1 (0.1%)	1 (0.1%)
DIPENTEN	1 (0.1%)	0
HOMEOPATHICS NOS	0	1 (0.1%)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA	1 (0.1%)	0
SODIUM ZIRCONIUM CYCLOSILICATE	1 (0.1%)	0
UROLOGICALS	12 (1.6%)	8 (1.1%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	6 (0.8%)	6 (0.8%)
TAMSULOSIN	5 (0.7%)	3 (0.4%)
TAMSULOSIN HYDROCHLORIDE	1 (0.1%)	3 (0.4%)
DRUGS USED IN ERECTILE DYSFUNCTION	4 (0.5%)	0
SILDENAFIL	3 (0.4%)	0
TADALAFIL	1 (0.1%)	0
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	1 (0.1%)	2 (0.3%)
FINASTERIDE	1 (0.1%)	2 (0.3%)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1%)	0
OXYBUTYNIN HYDROCHLORIDE	1 (0.1%)	0
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	0	1 (0.1%)
TADALAFIL	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
URINARY CONCREMENT SOLVENTS	1 (0.1%)	0
SODIUM BICARBONATE	1 (0.1%)	0
CARDIAC THERAPY	13 (1.7%)	6 (0.8%)
ADRENERGIC AND DOPAMINERGIC AGENTS	2 (0.3%)	3 (0.4%)
EPINEPHRINE	0	3 (0.4%)
PHENYLEPHRINE	2 (0.3%)	0
ORGANIC NITRATES	3 (0.4%)	2 (0.3%)
GLYCERYL TRINITRATE	2 (0.3%)	1 (0.1%)
ISOSORBIDE DINITRATE	1 (0.1%)	0
ISOSORBIDE MONONITRATE	0	1 (0.1%)
ANTIARRHYTHMICS, CLASS III	4 (0.5%)	0
AMIODARONE	2 (0.3%)	0
DOFETILIDE	2 (0.3%)	0
OTHER CARDIAC PREPARATIONS	3 (0.4%)	1 (0.1%)
UBIDECARENONE	3 (0.4%)	0
IVABRADINE HYDROCHLORIDE	0	1 (0.1%)
DIGITALIS GLYCOSIDES	1 (0.1%)	0
DIGOXIN	1 (0.1%)	0
OTHER VASODILATORS USED IN CARDIAC DISEASES	1 (0.1%)	0
SACUBITRIL	1 (0.1%)	0
MUSCLE RELAXANTS	8 (1.1%)	7 (1.0%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OTHER CENTRALLY ACTING AGENTS	7 (0.9%)	5 (0.7%)
CYCLOBENZAPRINE	4 (0.5%)	3 (0.4%)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
TIZANIDINE	2 (0.3%)	0
TIZANIDINE HYDROCHLORIDE	0	1 (0.1%)
CARBAMIC ACID ESTERS	0	2 (0.3%)
METHOCARBAMOL	0	2 (0.3%)
OTHER QUATERNARY AMMONIUM COMPOUNDS	1 (0.1%)	0
VECURONIUM BROMIDE	1 (0.1%)	0
ANTIGOUT PREPARATIONS	5 (0.7%)	8 (1.1%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	3 (0.4%)	6 (0.8%)
ALLOPURINOL	3 (0.4%)	6 (0.8%)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	2 (0.3%)	3 (0.4%)
COLCHICINE	2 (0.3%)	3 (0.4%)
IMMUNOSUPPRESSANTS	4 (0.5%)	8 (1.1%)
OTHER IMMUNOSUPPRESSANTS	3 (0.4%)	5 (0.7%)
HYDROXYCHLOROQUINE	2 (0.3%)	3 (0.4%)
METHOTREXATE	1 (0.1%)	2 (0.3%)
AZATHIOPRINE	0	1 (0.1%)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	0	3 (0.4%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ADALIMUMAB	0	2 (0.3%)
ETANERCEPT	0	1 (0.1%)
CALCINEURIN INHIBITORS	1 (0.1%)	0
TACROLIMUS	1 (0.1%)	0
SELECTIVE IMMUNOSUPPRESSANTS	1 (0.1%)	0
MYCOPHENOLATE MOFETIL	1 (0.1%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	8 (1.1%)	3 (0.4%)
ELECTROLYTE SOLUTIONS	6 (0.8%)	2 (0.3%)
SODIUM CHLORIDE	6 (0.8%)	2 (0.3%)
MAGNESIUM SULFATE	2 (0.3%)	0
POTASSIUM CHLORIDE	1 (0.1%)	0
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1 (0.1%)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	3 (0.4%)	1 (0.1%)
POTASSIUM	1 (0.1%)	1 (0.1%)
POTASSIUM CHLORIDE	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
ANTIEPILEPTICS	5 (0.7%)	5 (0.7%)
OTHER ANTIEPILEPTICS	3 (0.4%)	2 (0.3%)
LEVETIRACETAM	2 (0.3%)	0
GABAPENTIN	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
LACOSAMIDE	0	1 (0.1%)
TOPIRAMATE	1 (0.1%)	0
CARBOXAMIDE DERIVATIVES	2 (0.3%)	1 (0.1%)
OXCARBAZEPINE	2 (0.3%)	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	1 (0.1%)	0
CLOBAZAM	1 (0.1%)	0
FATTY ACID DERIVATIVES	0	1 (0.1%)
VALPROATE SODIUM	0	1 (0.1%)
HYDANTOIN DERIVATIVES	0	1 (0.1%)
PHENYTOIN SODIUM	0	1 (0.1%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.5%)	5 (0.7%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.5%)	5 (0.7%)
SAMBUCUS NIGRA	0	2 (0.3%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.1%)	1 (0.1%)
BACOPA MONNIERI	1 (0.1%)	0
CURCUMA LONGA RHIZOME	1 (0.1%)	0
MALUS SPP. VINEGAR EXTRACT	1 (0.1%)	0
MITRAGYNA SPECIOSA	0	1 (0.1%)
PRUNUS CERASUS	1 (0.1%)	0
WITHANIA SOMNIFERA	0	1 (0.1%)
ANTIANEMIC PREPARATIONS	6 (0.8%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
IRON BIVALENT, ORAL PREPARATIONS	4 (0.5%)	1 (0.1%)
FERROUS SULFATE	2 (0.3%)	1 (0.1%)
ASCORBIC ACID;FERROUS FUMARATE	1 (0.1%)	0
IRON	1 (0.1%)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	3 (0.4%)	0
VITAMIN B12 NOS	3 (0.4%)	0
ANTIHYPERTENSIVES	5 (0.7%)	2 (0.3%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	1 (0.1%)	2 (0.3%)
DOXAZOSIN	0	1 (0.1%)
DOXAZOSIN MESILATE	1 (0.1%)	0
PRAZOSIN	0	1 (0.1%)
HYDRAZINOPHTHALAZINE DERIVATIVES	3 (0.4%)	0
HYDRALAZINE	3 (0.4%)	0
IMIDAZOLINE RECEPTOR AGONISTS	2 (0.3%)	0
CLONIDINE	1 (0.1%)	0
GUANFACINE HYDROCHLORIDE	1 (0.1%)	0
ANTI-PARKINSON DRUGS	4 (0.5%)	2 (0.3%)
DOPAMINE AGONISTS	3 (0.4%)	1 (0.1%)
PRAMIPEXOLE	2 (0.3%)	0
PRAMIPEXOLE DIHYDROCHLORIDE	0	1 (0.1%)
ROPINIROLE	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DOPA AND DOPA DERIVATIVES	2 (0.3%)	1 (0.1%)
CARBIDOPA	2 (0.3%)	1 (0.1%)
LEVODOPA	1 (0.1%)	0
ANTIEMETICS AND ANTINAUSEANTS	3 (0.4%)	3 (0.4%)
OTHER ANTIEMETICS	2 (0.3%)	1 (0.1%)
PROMETHAZINE	1 (0.1%)	1 (0.1%)
MECLOZINE	1 (0.1%)	0
SEROTONIN (5HT3) ANTAGONISTS	1 (0.1%)	2 (0.3%)
ONDANSETRON	1 (0.1%)	2 (0.3%)
IMMUNE SERA AND IMMUNOGLOBULINS	6 (0.8%)	0
SPECIFIC IMMUNOGLOBULINS	6 (0.8%)	0
HYPERIMMUNE PLASMA COVID-19	6 (0.8%)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (0.4%)	3 (0.4%)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (0.4%)	3 (0.4%)
PROBIOTICS NOS	2 (0.3%)	1 (0.1%)
QUERCETIN	1 (0.1%)	2 (0.3%)
ANTIDIARRHEALS, INTESTINAL	4 (0.5%)	1 (0.1%)
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
ANTIDIARRHEAL MICROORGANISMS	2 (0.3%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
BIFIDOBACTERIUM LACTIS;INULIN;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS PARACASEI;SACCHAROMYCES BOULARDII;TRANS-GALACTOOLIGOSACCHARIDE PROBIOTICS NOS	1 (0.1%)	0
SACCHAROMYCES BOULARDII	0	1 (0.1%)
AMINOSALICYLIC ACID AND SIMILAR AGENTS MESALAZINE	1 (0.1%) 1 (0.1%)	0 0
ANTIPROPULSIVES LOPERAMIDE	0 0	1 (0.1%) 1 (0.1%)
ORAL REHYDRATION SALT FORMULATIONS ELECTROLYTES NOS;GLUCOSE	1 (0.1%) 1 (0.1%)	0 0
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS CORTICOSTEROIDS, MODERATELY POTENT (GROUP II) TRIAMCINOLONE ACETONIDE	1 (0.1%) 1 (0.1%) 0	4 (0.5%) 3 (0.4%) 2 (0.3%)
DESONIDE TRIAMCINOLONE	1 (0.1%) 0	0 1 (0.1%)
CORTICOSTEROIDS, POTENT (GROUP III) HYDROCORTISONE	0 0	1 (0.1%) 1 (0.1%)
OPHTHALMOLOGICALS OTHER OPHTHALMOLOGICALS	5 (0.7%) 3 (0.4%)	0 0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ASCORBIC ACID;TOCOPHERYL ACETATE;XANTOXYL;ZEAXANTHIN;ZINC	1 (0.1%)	0
CARMELLOSE	1 (0.1%)	0
LIFITEGRAST	1 (0.1%)	0
PROSTAGLANDIN ANALOGUES	2 (0.3%)	0
LATANOPROST	2 (0.3%)	0
BETA BLOCKING AGENTS	1 (0.1%)	0
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	1 (0.1%)	0
Uncoded	4 (0.5%)	1 (0.1%)
Uncoded	4 (0.5%)	1 (0.1%)
Uncoded	3 (0.4%)	1 (0.1%)
BLINDED THERAPY	1 (0.1%)	0
DRUGS FOR CONSTIPATION	3 (0.4%)	1 (0.1%)
SOFTENERS, EMOLLIENTS	2 (0.3%)	1 (0.1%)
DOCUSATE SODIUM	2 (0.3%)	1 (0.1%)
OSMOTICALLY ACTING LAXATIVES	2 (0.3%)	0
MAGNESIUM HYDROXIDE	2 (0.3%)	0
LACTULOSE	1 (0.1%)	0
CONTACT LAXATIVES	1 (0.1%)	0
BISACODYL	1 (0.1%)	0
OTHER NERVOUS SYSTEM DRUGS	1 (0.1%)	3 (0.4%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANTIVERTIGO PREPARATIONS	1 (0.1%)	0
MECLOZINE	1 (0.1%)	0
DRUGS USED IN OPIOID DEPENDENCE	0	1 (0.1%)
NALTREXONE	0	1 (0.1%)
OTHER NERVOUS SYSTEM DRUGS	0	1 (0.1%)
GABAPENTIN	0	1 (0.1%)
OTHER PARASYMPATHOMIMETICS	0	1 (0.1%)
CEVIMELINE	0	1 (0.1%)
ANTHELMINTICS	2 (0.3%)	1 (0.1%)
AVERMECTINES	2 (0.3%)	1 (0.1%)
IVERMECTIN	2 (0.3%)	1 (0.1%)
ANTI-ACNE PREPARATIONS	1 (0.1%)	2 (0.3%)
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE	0	1 (0.1%)
DAPSONE	0	1 (0.1%)
RETINOIDS FOR TOPICAL USE IN ACNE	1 (0.1%)	0
TRETINOIN	1 (0.1%)	0
RETINOIDS FOR TREATMENT OF ACNE	0	1 (0.1%)
ISOTRETINOIN	0	1 (0.1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	2 (0.3%)	1 (0.1%)
CENTRALLY ACTING ANTIPOBESITY PRODUCTS	2 (0.3%)	1 (0.1%)
PHENTERMINE	2 (0.3%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ENDOCRINE THERAPY	2 (0.3%)	1 (0.1%)
AROMATASE INHIBITORS	1 (0.1%)	1 (0.1%)
,3'-DIINDOLYLMET HANE	0	1 (0.1%)
LETROZOLE	1 (0.1%)	0
ESTROGENS	1 (0.1%)	0
ESTRADIOL	1 (0.1%)	0
IMMUNOSTIMULANTS	3 (0.4%)	0
HERBAL IMMUNOMODULATORS	2 (0.3%)	0
ASCORBIC ACID;CALCIUM;CORDYCEPS SINENSIS;GANODERMA LUCIDUM;GRIFOLA FRONDOSA;HERICIUM ERINACEUS;VITAMIN D NOS	1 (0.1%)	0
ECHINACEA SPP.	1 (0.1%)	0
COLONY STIMULATING FACTORS	1 (0.1%)	0
FILGRASTIM	1 (0.1%)	0
OTHER GYNECOLOGICALS	3 (0.4%)	0
INTRAUTERINE CONTRACEPTIVES	2 (0.3%)	0
LEVONORGESTREL	2 (0.3%)	0
INTRAVAGINAL CONTRACEPTIVES	1 (0.1%)	0
ETHINYLESTRADIOL;ETONOGESTREL	1 (0.1%)	0
ANESTHETICS	2 (0.3%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OPIOID ANESTHETICS	2 (0.3%)	0
FENTANYL	2 (0.3%)	0
OTHER GENERAL ANESTHETICS	1 (0.1%)	0
PROPOFOL	1 (0.1%)	0
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	2 (0.3%)	0
OTHER ANTIBIOTICS FOR TOPICAL USE	1 (0.1%)	0
BACITRACIN	1 (0.1%)	0
OTHER CHEMOTHERAPEUTICS	1 (0.1%)	0
METRONIDAZOLE	1 (0.1%)	0
ANTINEOPLASTIC AGENTS	2 (0.3%)	0
MONOCLONAL ANTIBODIES	2 (0.3%)	0
RITUXIMAB	2 (0.3%)	0
VACCINES	1 (0.1%)	1 (0.1%)
INFLUENZA VACCINES	0	1 (0.1%)
INFLUENZA VACCINE	0	1 (0.1%)
OTHER VIRAL VACCINES	1 (0.1%)	0
COVID-19 VACCINE	1 (0.1%)	0
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ASCORBIC ACID	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANTIFUNGALS FOR DERMATOLOGICAL USE	0	1 (0.1%)
OTHER ANTIFUNGALS FOR TOPICAL USE	0	1 (0.1%)
TOLNAFTATE	0	1 (0.1%)
ANTIMYCOTICS FOR SYSTEMIC USE	1 (0.1%)	0
TRIAZOLE DERIVATIVES	1 (0.1%)	0
FLUCONAZOLE	1 (0.1%)	0
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0.1%)	0
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	1 (0.1%)	0
TRIMEBUTINE	1 (0.1%)	0
DRUGS FOR TREATMENT OF BONE DISEASES	0	1 (0.1%)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	0	1 (0.1%)
DENOSUMAB	0	1 (0.1%)
EMOLLIENTS AND PROTECTIVES	1 (0.1%)	0
ZINC PRODUCTS	1 (0.1%)	0
MENTHOL;ZINC OXIDE	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
OTHER DERMATOLOGICAL PREPARATIONS	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OTHER DERMATOLOGICALS	0	1 (0.1%)
FINASTERIDE	0	1 (0.1%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.1%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.1%)	0
AMINO ACIDS NOS;ANIMAL UNSPECIFIED;ASCORBIC ACID;CYANOCOBALAMIN;HERBAL NOS;MANGANESE;PHOSPHORUS;RETINOL PALMITATE;TOCOPHEROL	1 (0.1%)	0
PANCREATIC HORMONES	1 (0.1%)	0
GLYCOGENOLYTIC HORMONES	1 (0.1%)	0
GLUCAGON	1 (0.1%)	0
TONICS	1 (0.1%)	0
TONICS	1 (0.1%)	0
DIETARY SUPPLEMENT	1 (0.1%)	0
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0	1 (0.1%)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	0	1 (0.1%)
DICLOFENAC	0	1 (0.1%)

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Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant medication	46 (6.1%)	24 (3.3%)
CORTICOSTEROIDS FOR SYSTEMIC USE	28 (3.7%)	9 (1.2%)
GLUCOCORTICIDS	28 (3.7%)	9 (1.2%)
DEXAMETHASONE	20 (2.7%)	4 (0.5%)
PREDNISONE	5 (0.7%)	3 (0.4%)
METHYLPREDNISOLONE	2 (0.3%)	2 (0.3%)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	0	2 (0.3%)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (0.1%)	0
ANTIBACTERIALS FOR SYSTEMIC USE	25 (3.3%)	11 (1.5%)
MACROLIDES	13 (1.7%)	6 (0.8%)
AZITHROMYCIN	13 (1.7%)	6 (0.8%)
THIRD-GENERATION CEPHALOSPORINS	8 (1.1%)	6 (0.8%)
CEFTRIAZONE	7 (0.9%)	3 (0.4%)
CEFDINIR	2 (0.3%)	3 (0.4%)
FLUOROQUINOLONES	1 (0.1%)	2 (0.3%)
LEVOFLOXACIN	1 (0.1%)	2 (0.3%)
ANTIBACTERIALS FOR SYSTEMIC USE	1 (0.1%)	1 (0.1%)
BROAD SPECTRUM ANTIBIOTICS	1 (0.1%)	0
PENICILLIN NOS	0	1 (0.1%)

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Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	2 (0.3%)	0
AMOXICILLIN;CLAVULANIC ACID	1 (0.1%)	0
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	1 (0.1%)	0
PENICILLINS WITH EXTENDED SPECTRUM	1 (0.1%)	1 (0.1%)
AMOXICILLIN	1 (0.1%)	1 (0.1%)
CARBAPENEMS	1 (0.1%)	0
MEROPENEM	1 (0.1%)	0
FOURTH-GENERATION CEPHALOSPORINS	0	1 (0.1%)
CEFEPIME	0	1 (0.1%)
GLYCOPEPTIDE ANTIBACTERIALS	1 (0.1%)	0
VANCOMYCIN	1 (0.1%)	0
INTERMEDIATE-ACTING SULFONAMIDES	1 (0.1%)	0
SULFAMETHOXAZOLE	1 (0.1%)	0
LINCOSAMIDES	0	1 (0.1%)
LINCOMYCIN	0	1 (0.1%)
TETRACYCLINES	1 (0.1%)	0
DOXYCYCLINE	1 (0.1%)	0
ALL OTHER THERAPEUTIC PRODUCTS	14 (1.9%)	4 (0.5%)
MEDICAL GASES	14 (1.9%)	4 (0.5%)
OXYGEN	14 (1.9%)	4 (0.5%)

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANTIVIRALS FOR SYSTEMIC USE	11 (1.5%)	2 (0.3%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	10 (1.3%)	2 (0.3%)
REMDESIVIR	10 (1.3%)	2 (0.3%)
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	0
LY 3819253	1 (0.1%)	0
ANALGESICS	5 (0.7%)	4 (0.5%)
ANILIDES	4 (0.5%)	2 (0.3%)
PARACETAMOL	4 (0.5%)	2 (0.3%)
OTHER OPIOIDS	1 (0.1%)	1 (0.1%)
TRAMADOL	1 (0.1%)	1 (0.1%)
SALICYLIC ACID AND DERIVATIVES	0	1 (0.1%)
ACETYLSALICYLIC ACID	0	1 (0.1%)
ANTITHROMBOTIC AGENTS	5 (0.7%)	3 (0.4%)
HEPARIN GROUP	4 (0.5%)	2 (0.3%)
ENOXAPARIN	3 (0.4%)	0
ENOXAPARIN SODIUM	0	2 (0.3%)
HEPARIN SODIUM	1 (0.1%)	0
DIRECT FACTOR XA INHIBITORS	1 (0.1%)	1 (0.1%)
APIXABAN	1 (0.1%)	1 (0.1%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	1 (0.1%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ACETYLSALICYLIC ACID	0	1 (0.1%)
EPOPROSTENOL	1 (0.1%)	0
PRASUGREL	0	1 (0.1%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	5 (0.7%)	3 (0.4%)
ELECTROLYTE SOLUTIONS	4 (0.5%)	2 (0.3%)
SODIUM CHLORIDE	4 (0.5%)	2 (0.3%)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	2 (0.3%)	1 (0.1%)
POTASSIUM	0	1 (0.1%)
POTASSIUM CHLORIDE	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
COUGH AND COLD PREPARATIONS	7 (0.9%)	0
OPIUM ALKALOIDS AND DERIVATIVES	3 (0.4%)	0
BROMPHENIRAMINE;HYDROCODONE;PSEUDOEPHEDRIN E	1 (0.1%)	0
DEXTROMETHORPHAN	1 (0.1%)	0
HOMATROPINE;HYDROCODONE	1 (0.1%)	0
EXPECTORANTS	2 (0.3%)	0
GUAIFENESIN	2 (0.3%)	0
OTHER COUGH SUPPRESSANTS	2 (0.3%)	0
BENZONATATE	2 (0.3%)	0
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	6 (0.8%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	4 (0.5%)	1 (0.1%)
SALBUTAMOL	3 (0.4%)	0
SALBUTAMOL SULFATE	1 (0.1%)	1 (0.1%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1%)	0
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	1 (0.1%)	0
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	1 (0.1%)	0
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	1 (0.1%)	0
ANTIHISTAMINES FOR SYSTEMIC USE	4 (0.5%)	1 (0.1%)
AMINOALKYL ETHERS	1 (0.1%)	1 (0.1%)
DIPHENHYDRAMINE	1 (0.1%)	1 (0.1%)
PHENOTHIAZINE DERIVATIVES	2 (0.3%)	0
PROMETHAZINE	2 (0.3%)	0
SUBSTITUTED ALKYLAMINES	1 (0.1%)	0
BROMPHENIRAMINE	1 (0.1%)	0
DRUGS FOR ACID RELATED DISORDERS	3 (0.4%)	2 (0.3%)
PROTON PUMP INHIBITORS	2 (0.3%)	1 (0.1%)
PANTOPRAZOLE	2 (0.3%)	1 (0.1%)
H2-RECEPTOR ANTAGONISTS	1 (0.1%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
FAMOTIDINE	1 (0.1%)	1 (0.1%)
MINERAL SUPPLEMENTS	3 (0.4%)	2 (0.3%)
ZINC	2 (0.3%)	1 (0.1%)
ZINC SULFATE	1 (0.1%)	1 (0.1%)
ZINC	1 (0.1%)	0
MAGNESIUM	0	1 (0.1%)
MAGNESIUM	0	1 (0.1%)
SODIUM	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	2 (0.3%)	1 (0.1%)
PROPIONIC ACID DERIVATIVES	1 (0.1%)	1 (0.1%)
IBUPROFEN	1 (0.1%)	1 (0.1%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	1 (0.1%)	0
KETOROLAC TROMETHAMINE	1 (0.1%)	0
DRUGS USED IN DIABETES	2 (0.3%)	1 (0.1%)
BIGUANIDES	1 (0.1%)	1 (0.1%)
METFORMIN	1 (0.1%)	1 (0.1%)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (0.1%)	0
INSULIN LISPRO	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
INSULIN GLARGINE	1 (0.1%)	0
IMMUNE SERA AND IMMUNOGLOBULINS	3 (0.4%)	0
SPECIFIC IMMUNOGLOBULINS	3 (0.4%)	0
HYPERIMMUNE PLASMA COVID-19	3 (0.4%)	0
MUSCLE RELAXANTS	3 (0.4%)	0
OTHER CENTRALLY ACTING AGENTS	2 (0.3%)	0
CYCLOBENZAPRINE	1 (0.1%)	0
CYCLOBENZAPRINE HYDROCHLORIDE	1 (0.1%)	0
OTHER QUATERNARY AMMONIUM COMPOUNDS	1 (0.1%)	0
VECURONIUM BROMIDE	1 (0.1%)	0
VITAMINS	2 (0.3%)	1 (0.1%)
ASCORBIC ACID (VITAMIN C), PLAIN	1 (0.1%)	1 (0.1%)
ASCORBIC ACID	1 (0.1%)	1 (0.1%)
COMBINATIONS OF VITAMINS	1 (0.1%)	0
ASCORBIC ACID;VITAMIN D NOS	1 (0.1%)	0
VITAMIN B-COMPLEX WITH VITAMIN C	0	1 (0.1%)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	0	1 (0.1%)
VITAMIN D AND ANALOGUES	0	1 (0.1%)
COLECALCIFEROL	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANESTHETICS	2 (0.3%)	0
OPIOID ANESTHETICS	2 (0.3%)	0
FENTANYL	2 (0.3%)	0
OTHER GENERAL ANESTHETICS	1 (0.1%)	0
PROPOFOL	1 (0.1%)	0
ANTIEMETICS AND ANTINAUSEANTS	1 (0.1%)	1 (0.1%)
SEROTONIN (5HT3) ANTAGONISTS	1 (0.1%)	1 (0.1%)
ONDANSETRON	1 (0.1%)	1 (0.1%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	0	2 (0.3%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	0	1 (0.1%)
TRIAMCINOLONE	0	1 (0.1%)
CORTICOSTEROIDS, POTENT (GROUP III)	0	1 (0.1%)
HYDROCORTISONE	0	1 (0.1%)
DIURETICS	1 (0.1%)	1 (0.1%)
ALDOSTERONE ANTAGONISTS	0	1 (0.1%)
SPIRONOLACTONE	0	1 (0.1%)
SULFONAMIDES, PLAIN	1 (0.1%)	0
FUROSEMIDE	1 (0.1%)	0
PSYCHOLEPTICS	1 (0.1%)	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	1 (0.1%)	0
LORAZEPAM	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DIPHENYLMETHANE DERIVATIVES	0	1 (0.1%)
HYDROXYZINE	0	1 (0.1%)
OTHER ANXIOLYTICS	0	1 (0.1%)
DULOXETINE HYDROCHLORIDE	0	1 (0.1%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	0	1 (0.1%)
ACE INHIBITORS, PLAIN	0	1 (0.1%)
LISINOPRIL	0	1 (0.1%)
ANTIDIARRHEALS, INTESTINAL	0	1 (0.1%)
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
ANTIDIARRHEAL MICROORGANISMS	0	1 (0.1%)
SACCHAROMYCES BOULARDII	0	1 (0.1%)
ANTIPROPULSIVES	0	1 (0.1%)
LOPERAMIDE	0	1 (0.1%)
BETA BLOCKING AGENTS	0	1 (0.1%)
ALPHA AND BETA BLOCKING AGENTS	0	1 (0.1%)
CARVEDILOL	0	1 (0.1%)
CARDIAC THERAPY	1 (0.1%)	0
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (0.1%)	0
PHENYLEPHRINE	1 (0.1%)	0
ANTIARRHYTHMICS, CLASS III	1 (0.1%)	0
AMIODARONE	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
LIPID MODIFYING AGENTS	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS	0	1 (0.1%)
ATORVASTATIN	0	1 (0.1%)
PANCREATIC HORMONES	1 (0.1%)	0
GLYCOGENOLYTIC HORMONES	1 (0.1%)	0
GLUCAGON	1 (0.1%)	0
THYROID THERAPY	1 (0.1%)	0
THYROID HORMONES	1 (0.1%)	0
LEVOTHYROXINE SODIUM	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant medication	445 (59.5%)	445 (60.5%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	141 (18.9%)	150 (20.4%)
ACE INHIBITORS, PLAIN	74 (9.9%)	74 (10.1%)
LISINOPRIL	64 (8.6%)	54 (7.3%)
ENALAPRIL	6 (0.8%)	7 (1.0%)
BENAZEPRIL	1 (0.1%)	6 (0.8%)
CAPTOPRIL	0	5 (0.7%)
RAMIPRIL	1 (0.1%)	2 (0.3%)
BENAZEPRIL HYDROCHLORIDE	1 (0.1%)	0
FOSINOPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	62 (8.3%)	69 (9.4%)
LOSARTAN	47 (6.3%)	45 (6.1%)
VALSARTAN	7 (0.9%)	6 (0.8%)
OLMESARTAN	3 (0.4%)	4 (0.5%)
IRBESARTAN	2 (0.3%)	4 (0.5%)
TELMISARTAN	2 (0.3%)	4 (0.5%)
OLMESARTAN MEDOXOMIL	2 (0.3%)	3 (0.4%)
LOSARTAN POTASSIUM	0	2 (0.3%)
AZILSARTAN KAMEDOXOMIL	0	1 (0.1%)
ACE INHIBITORS AND DIURETICS	2 (0.3%)	3 (0.4%)
HYDROCHLOROTHIAZIDE;LISINOPRIL	2 (0.3%)	3 (0.4%)

Clinical cut-off: 18Feb2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	2 (0.3%)	1 (0.1%)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	2 (0.3%)	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	0	2 (0.3%)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	0	1 (0.1%)
HYDROCHLOROTHIAZIDE;VALSARTAN	0	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	0	1 (0.1%)
AMLODIPINE BESILATE;VALSARTAN	0	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS	1 (0.1%)	0
SACUBITRIL VALSARTAN SODIUM HYDRATE	1 (0.1%)	0
ANALGESICS	151 (20.2%)	137 (18.6%)
ANILIDES	137 (18.3%)	120 (16.3%)
PARACETAMOL	125 (16.7%)	115 (15.6%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	8 (1.1%)	3 (0.4%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE HYDROCHLORIDE	7 (0.9%)	2 (0.3%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	2 (0.3%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
CAFFEINE;PARACETAMOL	1 (0.1%)	0
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYL EPHRINE HYDROCHLORIDE	0	1 (0.1%)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;P HENYLEPHRINE	1 (0.1%)	0
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRIN E	1 (0.1%)	0
DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0
IBUPROFEN;PARACETAMOL	0	1 (0.1%)
PARACETAMOL;PHENYLEPHRINE	0	1 (0.1%)
OTHER ANALGESICS AND ANTIPYRETICS	8 (1.1%)	10 (1.4%)
GABAPENTIN	7 (0.9%)	9 (1.2%)
DULOXETINE	1 (0.1%)	0
PREGABALIN	0	1 (0.1%)
SALICYLIC ACID AND DERIVATIVES	5 (0.7%)	2 (0.3%)
ACETYLSALICYLIC ACID	5 (0.7%)	2 (0.3%)
OTHER ANTIMIGRAINE PREPARATIONS	0	6 (0.8%)

Clinical cut-off: 18Feb2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
AMITRIPTYLINE	0	2 (0.3%)
METOPROLOL	0	2 (0.3%)
TOPIRAMATE	0	2 (0.3%)
SELECTIVE SEROTONIN (5HT1) AGONISTS	3 (0.4%)	3 (0.4%)
SUMATRIPTAN	2 (0.3%)	3 (0.4%)
SUMATRIPTAN SUCCINATE	1 (0.1%)	0
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	2 (0.3%)	2 (0.3%)
HYDROCODONE BITARTRATE;PARACETAMOL	1 (0.1%)	1 (0.1%)
CODEINE;PARACETAMOL	0	1 (0.1%)
HYDROCODONE;PARACETAMOL	1 (0.1%)	0
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS	0	3 (0.4%)
ERENUMAB	0	1 (0.1%)
FREMANEZUMAB	0	1 (0.1%)
GALCANEZUMAB	0	1 (0.1%)
NATURAL OPIUM ALKALOIDS	1 (0.1%)	2 (0.3%)
OXYCODONE	1 (0.1%)	1 (0.1%)
MORPHINE	0	1 (0.1%)
OTHER OPIOIDS	0	1 (0.1%)
TRAMADOL	0	1 (0.1%)
PYRAZOLONES	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
METAMIZOLE	0	1 (0.1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	86 (11.5%)	77 (10.5%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	57 (7.6%)	56 (7.6%)
SALBUTAMOL	51 (6.8%)	50 (6.8%)
SALBUTAMOL SULFATE	4 (0.5%)	3 (0.4%)
FORMOTEROL	1 (0.1%)	1 (0.1%)
LEVOSALBUTAMOL	1 (0.1%)	1 (0.1%)
LEVOSALBUTAMOL HYDROCHLORIDE	1 (0.1%)	0
LEVOSALBUTAMOL TARTRATE	0	1 (0.1%)
PROCATEROL HYDROCHLORIDE	0	1 (0.1%)
SALMETEROL	0	1 (0.1%)
LEUKOTRIENE RECEPTOR ANTAGONISTS	12 (1.6%)	17 (2.3%)
MONTELUKAST	6 (0.8%)	9 (1.2%)
MONTELUKAST SODIUM	6 (0.8%)	8 (1.1%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	19 (2.5%)	8 (1.1%)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	8 (1.1%)	6 (0.8%)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	6 (0.8%)	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE	5 (0.7%)	0
FLUTICASONE PROPIONATE;SALMETEROL	0	1 (0.1%)
ANTICHOLINERGICS	7 (0.9%)	6 (0.8%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
IPRATROPIUM BROMIDE	4 (0.5%)	1 (0.1%)
IPRATROPIUM	1 (0.1%)	3 (0.4%)
TIOTROPIUM BROMIDE	1 (0.1%)	1 (0.1%)
GLYCOPYRRONIUM	0	1 (0.1%)
UMECLIDINIUM BROMIDE	1 (0.1%)	0
GLUCOCORTICOIDS	8 (1.1%)	5 (0.7%)
FLUTICASONE	4 (0.5%)	0
FLUTICASONE PROPIONATE	2 (0.3%)	2 (0.3%)
BUDESONIDE	1 (0.1%)	1 (0.1%)
BECLOMETASONE DIPROPIONATE	0	1 (0.1%)
CICLESONIDE	0	1 (0.1%)
MOMETASONE FUROATE	1 (0.1%)	0
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	4 (0.5%)	4 (0.5%)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	2 (0.3%)	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	0	1 (0.1%)
IPRATROPIUM BROMIDE;SALBUTAMOL	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	1 (0.1%)	0
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	1 (0.1%)	0
UMECLIDINIUM;VILANTEROL	0	1 (0.1%)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0	1 (0.1%)
OMALIZUMAB	0	1 (0.1%)
LIPID MODIFYING AGENTS	64 (8.6%)	76 (10.3%)
HMG COA REDUCTASE INHIBITORS	59 (7.9%)	73 (9.9%)
ATORVASTATIN	21 (2.8%)	35 (4.8%)
SIMVASTATIN	11 (1.5%)	12 (1.6%)
ROSUVASTATIN	7 (0.9%)	10 (1.4%)
ROSUVASTATIN CALCIUM	4 (0.5%)	10 (1.4%)
ATORVASTATIN CALCIUM	7 (0.9%)	4 (0.5%)
PRAVASTATIN	4 (0.5%)	3 (0.4%)
LOVASTATIN	2 (0.3%)	1 (0.1%)
PITAVASTATIN CALCIUM	2 (0.3%)	0
PRAVASTATIN SODIUM	1 (0.1%)	0
OTHER LIPID MODIFYING AGENTS	3 (0.4%)	9 (1.2%)
EZETIMIBE	1 (0.1%)	4 (0.5%)
FISH OIL	2 (0.3%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
EICOSAPENTAENOIC ACID ETHYL ESTER	0	2 (0.3%)
OMEGA-3-ACID ETHYL ESTER	0	1 (0.1%)
SITOSTEROL	0	1 (0.1%)
FIBRATES	2 (0.3%)	3 (0.4%)
FENOFIBRATE	2 (0.3%)	2 (0.3%)
GEMFIBROZIL	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS IN COMBINATION WITH OTHER LIPID MODIFYING AGENTS	2 (0.3%)	0
EZETIMIBE;SIMVASTATIN	2 (0.3%)	0
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	1 (0.1%)	0
CARTHAMUS TINCTORIUS OIL	1 (0.1%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	67 (9.0%)	70 (9.5%)
PROPIONIC ACID DERIVATIVES	56 (7.5%)	59 (8.0%)
IBUPROFEN	49 (6.6%)	50 (6.8%)
NAPROXEN	3 (0.4%)	6 (0.8%)
NAPROXEN SODIUM	5 (0.7%)	2 (0.3%)
HYDROCODONE BITARTRATE;IBUPROFEN	0	1 (0.1%)
OXICAMS	7 (0.9%)	3 (0.4%)
MELOXICAM	7 (0.9%)	3 (0.4%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	3 (0.4%)	4 (0.5%)
DICLOFENAC	2 (0.3%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DICLOFENAC SODIUM	1 (0.1%)	1 (0.1%)
ETODOLAC	0	2 (0.3%)
DICLOFENAC POTASSIUM	1 (0.1%)	0
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	1 (0.1%)	5 (0.7%)
BENZYDAMINE	1 (0.1%)	1 (0.1%)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	0	2 (0.3%)
BENZYDAMINE HYDROCHLORIDE	0	1 (0.1%)
GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	0	1 (0.1%)
COXIBS	2 (0.3%)	0
CELECOXIB	2 (0.3%)	0
DRUGS USED IN DIABETES	54 (7.2%)	55 (7.5%)
BIGUANIDES	39 (5.2%)	41 (5.6%)
METFORMIN	36 (4.8%)	41 (5.6%)
METFORMIN HYDROCHLORIDE	3 (0.4%)	0
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	12 (1.6%)	6 (0.8%)
INSULIN LISPRO	6 (0.8%)	3 (0.4%)
INSULIN ASPART	4 (0.5%)	2 (0.3%)
INSULIN	1 (0.1%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
INSULIN HUMAN	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	8 (1.1%)	7 (1.0%)
INSULIN GLARGINE	5 (0.7%)	6 (0.8%)
INSULIN DEGLUDEC	1 (0.1%)	1 (0.1%)
INSULIN DETEMIR	2 (0.3%)	0
SULFONYLUREAS	9 (1.2%)	6 (0.8%)
GLIPIZIDE	7 (0.9%)	5 (0.7%)
GLIMEPIRIDE	2 (0.3%)	1 (0.1%)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	4 (0.5%)	7 (1.0%)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	2 (0.3%)	4 (0.5%)
EMPAGLIFLOZIN	2 (0.3%)	1 (0.1%)
CANAGLIFLOZIN	0	2 (0.3%)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES	7 (0.9%)	3 (0.4%)
DULAGLUTIDE	3 (0.4%)	1 (0.1%)
SEMAGLUTIDE	2 (0.3%)	2 (0.3%)
EXENATIDE	1 (0.1%)	0
LIRAGLUTIDE	1 (0.1%)	0
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	1 (0.1%)	4 (0.5%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	0	2 (0.3%)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	1 (0.1%)	1 (0.1%)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	0	1 (0.1%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	3 (0.4%)	2 (0.3%)
SITAGLIPTIN	2 (0.3%)	2 (0.3%)
LINAGLIPTIN	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	2 (0.3%)	1 (0.1%)
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	2 (0.3%)	1 (0.1%)
ALPHA GLUCOSIDASE INHIBITORS	1 (0.1%)	0
ACARBOSE	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	0	1 (0.1%)
INSULIN ASPART;INSULIN ASPART PROTAMINE	0	1 (0.1%)
THIAZOLIDINEDIONES	1 (0.1%)	0
PIOGLITAZONE HYDROCHLORIDE	1 (0.1%)	0
BETA BLOCKING AGENTS	43 (5.7%)	42 (5.7%)
BETA BLOCKING AGENTS, SELECTIVE	27 (3.6%)	36 (4.9%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
METOPROLOL	11 (1.5%)	19 (2.6%)
ATENOLOL	11 (1.5%)	7 (1.0%)
NEBIVOLOL HYDROCHLORIDE	1 (0.1%)	5 (0.7%)
METOPROLOL TARTRATE	2 (0.3%)	3 (0.4%)
METOPROLOL SUCCINATE	1 (0.1%)	2 (0.3%)
BISOPROLOL	1 (0.1%)	0
ALPHA AND BETA BLOCKING AGENTS	14 (1.9%)	5 (0.7%)
CARVEDILOL	12 (1.6%)	5 (0.7%)
LABETALOL	2 (0.3%)	0
LABETALOL HYDROCHLORIDE	1 (0.1%)	0
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0.1%)	2 (0.3%)
SOTALOL	0	2 (0.3%)
PROPRANOLOL	1 (0.1%)	0
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	1 (0.1%)	0
BISOPROLOL;HYDROCHLOROTHIAZIDE	1 (0.1%)	0
CALCIUM CHANNEL BLOCKERS	36 (4.8%)	47 (6.4%)
DIHYDROPYRIDINE DERIVATIVES	33 (4.4%)	44 (6.0%)
AMLODIPINE	26 (3.5%)	37 (5.0%)
AMLODIPINE BESILATE	4 (0.5%)	4 (0.5%)
NIFEDIPINE	3 (0.4%)	2 (0.3%)
FELODIPINE	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
BENZOTHAZEPINE DERIVATIVES	2 (0.3%)	3 (0.4%)
DILTIAZEM	2 (0.3%)	2 (0.3%)
DILTIAZEM HYDROCHLORIDE	0	1 (0.1%)
PHENYLALKYLAMINE DERIVATIVES	1 (0.1%)	0
VERAPAMIL	1 (0.1%)	0
DIURETICS	43 (5.7%)	36 (4.9%)
THIAZIDES, PLAIN	29 (3.9%)	28 (3.8%)
HYDROCHLOROTHIAZIDE	29 (3.9%)	28 (3.8%)
SULFONAMIDES, PLAIN	9 (1.2%)	7 (1.0%)
FUROSEMIDE	3 (0.4%)	5 (0.7%)
CHLORTALIDONE	3 (0.4%)	1 (0.1%)
BUMETANIDE	1 (0.1%)	1 (0.1%)
INDAPAMIDE	2 (0.3%)	0
TORASEMIDE	1 (0.1%)	0
OTHER POTASSIUM-SPARING AGENTS	1 (0.1%)	2 (0.3%)
TRIAMTERENE	1 (0.1%)	2 (0.3%)
ALDOSTERONE ANTAGONISTS	1 (0.1%)	1 (0.1%)
SPIRONOLACTONE	1 (0.1%)	1 (0.1%)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	2 (0.3%)	0
HYDROCHLOROTHIAZIDE;TRIAMTERENE	2 (0.3%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DIURETICS	1 (0.1%)	0
ISOSORBIDE	1 (0.1%)	0
PSYCHOANALEPTICS	30 (4.0%)	40 (5.4%)
OTHER ANTIDEPRESSANTS	10 (1.3%)	20 (2.7%)
TRAZODONE	2 (0.3%)	6 (0.8%)
LAMOTRIGINE	4 (0.5%)	2 (0.3%)
BUPROPION	0	5 (0.7%)
BUPROPION HYDROCHLORIDE	3 (0.4%)	2 (0.3%)
DULOXETINE	2 (0.3%)	2 (0.3%)
DULOXETINE HYDROCHLORIDE	1 (0.1%)	0
MIRTAZAPINE	0	1 (0.1%)
VENLAFAXINE	0	1 (0.1%)
VENLAFAXINE HYDROCHLORIDE	0	1 (0.1%)
VILAZODONE HYDROCHLORIDE	1 (0.1%)	0
VORTIOXETINE HYDROBROMIDE	0	1 (0.1%)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	10 (1.3%)	13 (1.8%)
CITALOPRAM	2 (0.3%)	5 (0.7%)
SERTRALINE	3 (0.4%)	3 (0.4%)
ESCITALOPRAM OXALATE	3 (0.4%)	1 (0.1%)
FLUOXETINE HYDROCHLORIDE	0	2 (0.3%)
CITALOPRAM HYDROBROMIDE	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ESCITALOPRAM	0	1 (0.1%)
FLUOXETINE	1 (0.1%)	0
SERTRALINE HYDROCHLORIDE	0	1 (0.1%)
CENTRALLY ACTING SYMPATHOMIMETICS	10 (1.3%)	7 (1.0%)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	7 (0.9%)	4 (0.5%)
LISDEXAMFETAMINE MESILATE	1 (0.1%)	2 (0.3%)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
LISDEXAMFETAMINE	1 (0.1%)	0
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	2 (0.3%)	3 (0.4%)
AMITRIPTYLINE	2 (0.3%)	2 (0.3%)
DOXEPIN	0	1 (0.1%)
ANTICHOLINESTERASES	0	2 (0.3%)
DONEPEZIL	0	2 (0.3%)
XANTHINE DERIVATIVES	0	2 (0.3%)
CAFFEINE	0	2 (0.3%)
OTHER ANTI-DEMENTIA DRUGS	0	1 (0.1%)
MEMANTINE	0	1 (0.1%)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	1 (0.1%)	0
GUANFACINE	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANTITHROMBOTIC AGENTS	35 (4.7%)	34 (4.6%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	23 (3.1%)	29 (3.9%)
ACETYLSALICYLIC ACID	22 (2.9%)	24 (3.3%)
CLOPIDOGREL	1 (0.1%)	5 (0.7%)
CLOPIDOGREL BISULFATE	0	3 (0.4%)
PRASUGREL	0	1 (0.1%)
PRASUGREL HYDROCHLORIDE	0	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	11 (1.5%)	6 (0.8%)
APIXABAN	8 (1.1%)	4 (0.5%)
RIVAROXABAN	3 (0.4%)	2 (0.3%)
HEPARIN GROUP	2 (0.3%)	0
ENOXAPARIN	2 (0.3%)	0
VITAMIN K ANTAGONISTS	0	1 (0.1%)
WARFARIN	0	1 (0.1%)
DRUGS FOR ACID RELATED DISORDERS	37 (4.9%)	29 (3.9%)
PROTON PUMP INHIBITORS	35 (4.7%)	28 (3.8%)
OMEPRAZOLE	24 (3.2%)	12 (1.6%)
PANTOPRAZOLE	6 (0.8%)	8 (1.1%)
ESOMEPRAZOLE	4 (0.5%)	4 (0.5%)
LANSOPRAZOLE	1 (0.1%)	1 (0.1%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0	2 (0.3%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DEXLANSOPRAZOLE	0	1 (0.1%)
H2-RECEPTOR ANTAGONISTS	3 (0.4%)	0
FAMOTIDINE	3 (0.4%)	0
ALUMINIUM COMPOUNDS	1 (0.1%)	0
ALUMINIUM HYDROXIDE	1 (0.1%)	0
ANTACIDS WITH SODIUM BICARBONATE	0	1 (0.1%)
SODIUM BICARBONATE	0	1 (0.1%)
CALCIUM COMPOUNDS	1 (0.1%)	0
CALCIUM CARBONATE	1 (0.1%)	0
THYROID THERAPY	27 (3.6%)	34 (4.6%)
THYROID HORMONES	27 (3.6%)	31 (4.2%)
LEVOTHYROXINE	17 (2.3%)	22 (3.0%)
LEVOTHYROXINE SODIUM	10 (1.3%)	9 (1.2%)
LIOthyRONINE SODIUM	1 (0.1%)	0
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0	3 (0.4%)
THIAMAZOLE	0	3 (0.4%)
ANTIBACTERIALS FOR SYSTEMIC USE	28 (3.7%)	32 (4.3%)
MACROLIDES	18 (2.4%)	22 (3.0%)
AZITHROMYCIN	17 (2.3%)	21 (2.9%)
AZITHROMYCIN DIHYDRATE	1 (0.1%)	0
CLARITHROMYCIN	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
TETRACYCLINES	5 (0.7%)	2 (0.3%)
DOXYCYCLINE	4 (0.5%)	2 (0.3%)
MINOCYCLINE	1 (0.1%)	0
FLUOROQUINOLONES	2 (0.3%)	4 (0.5%)
LEVOFLOXACIN	1 (0.1%)	4 (0.5%)
CIPROFLOXACIN	1 (0.1%)	0
THIRD-GENERATION CEPHALOSPORINS	1 (0.1%)	2 (0.3%)
CEFTRIAZONE	1 (0.1%)	1 (0.1%)
CEFDINIR	0	1 (0.1%)
PENICILLINS WITH EXTENDED SPECTRUM	0	2 (0.3%)
AMOXICILLIN	0	1 (0.1%)
AMPICILLIN	0	1 (0.1%)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	1 (0.1%)	0
AMOXICILLIN;CLAVULANIC ACID	1 (0.1%)	0
NITROFURAN DERIVATIVES	0	1 (0.1%)
NITROFURANTOIN	0	1 (0.1%)
TRIMETHOPRIM AND DERIVATIVES	1 (0.1%)	0
TRIMETHOPRIM	1 (0.1%)	0
PSYCHOLEPTICS	27 (3.6%)	29 (3.9%)
OTHER ANXIOLYTICS	7 (0.9%)	13 (1.8%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ESCITALOPRAM	1 (0.1%)	6 (0.8%)
ESCITALOPRAM OXALATE	1 (0.1%)	2 (0.3%)
SERTRALINE	2 (0.3%)	1 (0.1%)
PAROXETINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
AMITRIPTYLINE	0	1 (0.1%)
FLUOXETINE	0	1 (0.1%)
LAVANDULA ANGUSTIFOLIA ESSENTIAL OIL	1 (0.1%)	0
PAROXETINE	1 (0.1%)	0
PROPRANOLOL	0	1 (0.1%)
SERTRALINE HYDROCHLORIDE	0	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	7 (0.9%)	11 (1.5%)
LORAZEPAM	1 (0.1%)	5 (0.7%)
ALPRAZOLAM	3 (0.4%)	1 (0.1%)
CLONAZEPAM	2 (0.3%)	2 (0.3%)
TEMAZEPAM	1 (0.1%)	2 (0.3%)
DIAZEPAM	0	1 (0.1%)
MELATONIN RECEPTOR AGONISTS	7 (0.9%)	2 (0.3%)
MELATONIN	7 (0.9%)	2 (0.3%)
BENZODIAZEPINE RELATED DRUGS	2 (0.3%)	3 (0.4%)
ZOLPIDEM TARTRATE	1 (0.1%)	2 (0.3%)
ESZOPICLONE	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ZOLPIDEM	0	1 (0.1%)
OTHER ANTIPSYCHOTICS	2 (0.3%)	3 (0.4%)
ARIPIPRAZOLE	1 (0.1%)	3 (0.4%)
VALPROATE SEMISODIUM	1 (0.1%)	0
AZASPIRODECANEDIONE DERIVATIVES	3 (0.4%)	0
BUSPIRONE	2 (0.3%)	0
BUSPIRONE HYDROCHLORIDE	1 (0.1%)	0
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	3 (0.4%)	0
QUETIAPINE FUMARATE	2 (0.3%)	0
OLANZAPINE	1 (0.1%)	0
OTHER HYPNOTICS AND SEDATIVES	1 (0.1%)	1 (0.1%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (0.1%)
DOXEPIN	1 (0.1%)	0
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	2 (0.3%)	0
PROCHLORPERAZINE	2 (0.3%)	0
BARBITURATES, PLAIN	0	1 (0.1%)
BUTALBITAL	0	1 (0.1%)
DIPHENYLMETHANE DERIVATIVES	0	1 (0.1%)
HYDROXYZINE EMBONATE	0	1 (0.1%)
COUGH AND COLD PREPARATIONS	24 (3.2%)	17 (2.3%)
EXPECTORANTS	10 (1.3%)	7 (1.0%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
GUAIFENESIN	10 (1.3%)	7 (1.0%)
OPIUM ALKALOIDS AND DERIVATIVES	4 (0.5%)	6 (0.8%)
DEXTROMETHORPHAN	2 (0.3%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (0.1%)	2 (0.3%)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
CHLORPHENAMINE;HYDROCODONE BITARTRATE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PROMETHAZINE HYDROCHLORIDE	0	1 (0.1%)
OPIUM DERIVATIVES AND EXPECTORANTS	3 (0.4%)	5 (0.7%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	1 (0.1%)	2 (0.3%)
CODEINE PHOSPHATE;GUAIFENESIN	1 (0.1%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	0	2 (0.3%)
DEXTROMETHORPHAN;GUAIFENESIN	1 (0.1%)	0
OTHER COUGH SUPPRESSANTS	5 (0.7%)	1 (0.1%)
BENZONATATE	5 (0.7%)	1 (0.1%)
COUGH AND COLD PREPARATIONS	2 (0.3%)	1 (0.1%)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
EUCALYPTUS GLOBULUS OIL;MENTHOL	1 (0.1%)	0
MUCOLYTICS	2 (0.3%)	1 (0.1%)
BROMHEXINE	1 (0.1%)	1 (0.1%)
ACETYLCYSTEINE	1 (0.1%)	0
ANTIHISTAMINES FOR SYSTEMIC USE	16 (2.1%)	18 (2.4%)
PIPERAZINE DERIVATIVES	9 (1.2%)	10 (1.4%)
CETIRIZINE	5 (0.7%)	5 (0.7%)
CETIRIZINE HYDROCHLORIDE	4 (0.5%)	5 (0.7%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	5 (0.7%)	4 (0.5%)
LORATADINE	2 (0.3%)	4 (0.5%)
FEXOFENADINE HYDROCHLORIDE	2 (0.3%)	0
EPINASTINE	1 (0.1%)	0
AMINOALKYL ETHERS	3 (0.4%)	2 (0.3%)
DOXYLAMINE SUCCINATE	1 (0.1%)	2 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (0.3%)	0
PHENOTHIAZINE DERIVATIVES	1 (0.1%)	1 (0.1%)
PROMETHAZINE	1 (0.1%)	1 (0.1%)
SUBSTITUTED ALKYLAMINES	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DEXBROMPHENIRAMINE	0	1 (0.1%)
VITAMINS	17 (2.3%)	17 (2.3%)
VITAMIN D AND ANALOGUES	14 (1.9%)	12 (1.6%)
VITAMIN D NOS	10 (1.3%)	8 (1.1%)
COLECALCIFEROL	4 (0.5%)	4 (0.5%)
ASCORBIC ACID (VITAMIN C), PLAIN	10 (1.3%)	13 (1.8%)
ASCORBIC ACID	10 (1.3%)	13 (1.8%)
NASAL PREPARATIONS	10 (1.3%)	13 (1.8%)
CORTICOSTEROIDS	5 (0.7%)	9 (1.2%)
FLUTICASONE PROPIONATE	3 (0.4%)	5 (0.7%)
FLUTICASONE	2 (0.3%)	2 (0.3%)
BUDESONIDE	0	1 (0.1%)
TRIAMCINOLONE ACETONIDE	0	1 (0.1%)
SYMPATHOMIMETICS	3 (0.4%)	2 (0.3%)
BROMPHENIRAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
PHENYLEPHRINE	1 (0.1%)	0
PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.1%)
PSEUDOEPHEDRINE	0	1 (0.1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
SYMPATHOMIMETICS, PLAIN	2 (0.3%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.1%)
PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
TETRYZOLINE	1 (0.1%)	0
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	1 (0.1%)	1 (0.1%)
AZELASTINE	1 (0.1%)	1 (0.1%)
OTHER NASAL PREPARATIONS	0	1 (0.1%)
IPRATROPIUM BROMIDE	0	1 (0.1%)
ANTIVIRALS FOR SYSTEMIC USE	12 (1.6%)	8 (1.1%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	9 (1.2%)	2 (0.3%)
VALACICLOVIR	3 (0.4%)	1 (0.1%)
REMDESIVIR	3 (0.4%)	0
VALACICLOVIR HYDROCHLORIDE	2 (0.3%)	1 (0.1%)
VALGANCICLOVIR HYDROCHLORIDE	1 (0.1%)	0
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	2 (0.3%)	5 (0.7%)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE	2 (0.3%)	3 (0.4%)
DOLUTEGRAVIR;LAMIVUDINE	0	1 (0.1%)
EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	0	1 (0.1%)
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
LY 3819253	1 (0.1%)	0
NEURAMINIDASE INHIBITORS	0	1 (0.1%)
OSELTAMIVIR	0	1 (0.1%)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
ABACAVIR	0	1 (0.1%)
UROLOGICALS	11 (1.5%)	8 (1.1%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	6 (0.8%)	6 (0.8%)
TAMSULOSIN	5 (0.7%)	3 (0.4%)
TAMSULOSIN HYDROCHLORIDE	1 (0.1%)	3 (0.4%)
DRUGS USED IN ERECTILE DYSFUNCTION	3 (0.4%)	0
SILDENAFIL	2 (0.3%)	0
TADALAFIL	1 (0.1%)	0
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	1 (0.1%)	2 (0.3%)
FINASTERIDE	1 (0.1%)	2 (0.3%)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1%)	0
OXYBUTYNIN HYDROCHLORIDE	1 (0.1%)	0
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	0	1 (0.1%)
TADALAFIL	0	1 (0.1%)
URINARY CONCREMENT SOLVENTS	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
SODIUM BICARBONATE	1 (0.1%)	0
MINERAL SUPPLEMENTS	7 (0.9%)	11 (1.5%)
ZINC	6 (0.8%)	9 (1.2%)
ZINC	5 (0.7%)	9 (1.2%)
ZINC ACETATE;ZINC GLUCONATE	1 (0.1%)	0
MAGNESIUM	1 (0.1%)	2 (0.3%)
MAGNESIUM	1 (0.1%)	2 (0.3%)
POTASSIUM	0	2 (0.3%)
POTASSIUM CHLORIDE	0	2 (0.3%)
CALCIUM	0	1 (0.1%)
CALCIUM	0	1 (0.1%)
SODIUM	1 (0.1%)	0
SODIUM	1 (0.1%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	10 (1.3%)	4 (0.5%)
GLUCOCORTICIODS	10 (1.3%)	4 (0.5%)
DEXAMETHASONE	6 (0.8%)	2 (0.3%)
PREDNISONE	2 (0.3%)	1 (0.1%)
METHYLPREDNISOLONE	1 (0.1%)	1 (0.1%)
CORTISONE	1 (0.1%)	0
CARDIAC THERAPY	9 (1.2%)	4 (0.5%)
ORGANIC NITRATES	3 (0.4%)	2 (0.3%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
GLYCERYL TRINITRATE	2 (0.3%)	1 (0.1%)
ISOSORBIDE DINITRATE	1 (0.1%)	0
ISOSORBIDE MONONITRATE	0	1 (0.1%)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (0.1%)	2 (0.3%)
EPINEPHRINE	0	2 (0.3%)
PHENYLEPHRINE	1 (0.1%)	0
ANTIARRHYTHMICS, CLASS III	3 (0.4%)	0
DOFETILIDE	2 (0.3%)	0
AMIODARONE	1 (0.1%)	0
DIGITALIS GLYCOSIDES	1 (0.1%)	0
DIGOXIN	1 (0.1%)	0
OTHER VASODILATORS USED IN CARDIAC DISEASES	1 (0.1%)	0
SACUBITRIL	1 (0.1%)	0
ANTIGOUT PREPARATIONS	5 (0.7%)	7 (1.0%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	3 (0.4%)	5 (0.7%)
ALLOPURINOL	3 (0.4%)	5 (0.7%)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	2 (0.3%)	3 (0.4%)
COLCHICINE	2 (0.3%)	3 (0.4%)
IMMUNOSUPPRESSANTS	4 (0.5%)	8 (1.1%)
OTHER IMMUNOSUPPRESSANTS	3 (0.4%)	5 (0.7%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
HYDROXYCHLOROQUINE	2 (0.3%)	3 (0.4%)
METHOTREXATE	1 (0.1%)	2 (0.3%)
AZATHIOPRINE	0	1 (0.1%)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	0	3 (0.4%)
ADALIMUMAB	0	2 (0.3%)
ETANERCEPT	0	1 (0.1%)
CALCINEURIN INHIBITORS	1 (0.1%)	0
TACROLIMUS	1 (0.1%)	0
SELECTIVE IMMUNOSUPPRESSANTS	1 (0.1%)	0
MYCOPHENOLATE MOFETIL	1 (0.1%)	0
MUSCLE RELAXANTS	5 (0.7%)	7 (1.0%)
OTHER CENTRALLY ACTING AGENTS	5 (0.7%)	5 (0.7%)
CYCLOBENZAPRINE	3 (0.4%)	3 (0.4%)
TIZANIDINE	2 (0.3%)	0
CYCLOBENZAPRINE HYDROCHLORIDE	0	1 (0.1%)
TIZANIDINE HYDROCHLORIDE	0	1 (0.1%)
CARBAMIC ACID ESTERS	0	2 (0.3%)
METHOCARBAMOL	0	2 (0.3%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	8 (1.1%)	4 (0.5%)
-OXOANDROSTEN (4) DERIVATIVES	2 (0.3%)	3 (0.4%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
TESTOSTERONE	1 (0.1%)	2 (0.3%)
TESTOSTERONE CIPIONATE	1 (0.1%)	1 (0.1%)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	3 (0.4%)	1 (0.1%)
ESTRADIOL	3 (0.4%)	1 (0.1%)
PREGNEN (4) DERIVATIVES	2 (0.3%)	0
PROGESTERONE	2 (0.3%)	0
ESTROGENS, COMBINATIONS WITH OTHER DRUGS	1 (0.1%)	0
BAZEDOXIFENE;ESTROGENS CONJUGATED	1 (0.1%)	0
PROGESTOGENS	0	1 (0.1%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.1%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	1 (0.1%)	0
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	1 (0.1%)	0
ANTIEPILEPTICS	5 (0.7%)	5 (0.7%)
OTHER ANTIEPILEPTICS	3 (0.4%)	2 (0.3%)
LEVETIRACETAM	2 (0.3%)	0
GABAPENTIN	0	1 (0.1%)
LACOSAMIDE	0	1 (0.1%)
TOPIRAMATE	1 (0.1%)	0
CARBOXAMIDE DERIVATIVES	2 (0.3%)	1 (0.1%)
OXCARBAZEPINE	2 (0.3%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
BENZODIAZEPINE DERIVATIVES	1 (0.1%)	0
CLOBAZAM	1 (0.1%)	0
FATTY ACID DERIVATIVES	0	1 (0.1%)
VALPROATE SODIUM	0	1 (0.1%)
HYDANTOIN DERIVATIVES	0	1 (0.1%)
PHENYTOIN SODIUM	0	1 (0.1%)
ANTI-PARKINSON DRUGS	4 (0.5%)	2 (0.3%)
DOPAMINE AGONISTS	3 (0.4%)	1 (0.1%)
PRAMIPEXOLE	2 (0.3%)	0
PRAMIPEXOLE DIHYDROCHLORIDE	0	1 (0.1%)
ROPINIROLE	1 (0.1%)	0
DOPA AND DOPA DERIVATIVES	2 (0.3%)	1 (0.1%)
CARBIDOPA	2 (0.3%)	1 (0.1%)
LEVODOPA	1 (0.1%)	0
ANTIHYPERTENSIVES	5 (0.7%)	1 (0.1%)
HYDRAZINOPHTHALAZINE DERIVATIVES	3 (0.4%)	0
HYDRALAZINE	3 (0.4%)	0
ALPHA-ADRENORECEPTOR ANTAGONISTS	1 (0.1%)	1 (0.1%)
DOXAZOSIN	0	1 (0.1%)
DOXAZOSIN MESILATE	1 (0.1%)	0
IMIDAZOLINE RECEPTOR AGONISTS	2 (0.3%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
CLONIDINE	1 (0.1%)	0
GUANFACINE HYDROCHLORIDE	1 (0.1%)	0
ALL OTHER THERAPEUTIC PRODUCTS	4 (0.5%)	1 (0.1%)
MEDICAL GASES	3 (0.4%)	0
OXYGEN	3 (0.4%)	0
OTHER THERAPEUTIC PRODUCTS	1 (0.1%)	1 (0.1%)
DIPENTEN	1 (0.1%)	0
HOMEOPATHICS NOS	0	1 (0.1%)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA	1 (0.1%)	0
SODIUM ZIRCONIUM CYCLOSILICATE	1 (0.1%)	0
ANTIANEMIC PREPARATIONS	4 (0.5%)	1 (0.1%)
IRON BIVALENT, ORAL PREPARATIONS	3 (0.4%)	1 (0.1%)
FERROUS SULFATE	2 (0.3%)	1 (0.1%)
IRON	1 (0.1%)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	1 (0.1%)	0
VITAMIN B12 NOS	1 (0.1%)	0
OPHTHALMOLOGICALS	4 (0.5%)	0
OTHER OPHTHALMOLOGICALS	2 (0.3%)	0
ASCORBIC ACID;TOCOPHERYL ACETATE;XANTOXYL;ZEAXANTHIN;ZINC	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
LIFITEGRAST	1 (0.1%)	0
PROSTAGLANDIN ANALOGUES	2 (0.3%)	0
LATANOPROST	2 (0.3%)	0
BETA BLOCKING AGENTS	1 (0.1%)	0
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	1 (0.1%)	0
Uncoded	3 (0.4%)	1 (0.1%)
Uncoded	3 (0.4%)	1 (0.1%)
Uncoded	2 (0.3%)	1 (0.1%)
BLINDED THERAPY	1 (0.1%)	0
ANTHELMINTICS	2 (0.3%)	1 (0.1%)
AVERMECTINES	2 (0.3%)	1 (0.1%)
IVERMECTIN	2 (0.3%)	1 (0.1%)
ANTI-ACNE PREPARATIONS	1 (0.1%)	2 (0.3%)
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE	0	1 (0.1%)
DAPSONE	0	1 (0.1%)
RETINOIDS FOR TOPICAL USE IN ACNE	1 (0.1%)	0
TRETINOIN	1 (0.1%)	0
RETINOIDS FOR TREATMENT OF ACNE	0	1 (0.1%)
ISOTRETINOIN	0	1 (0.1%)
ANTIEMETICS AND ANTINAUSEANTS	2 (0.3%)	1 (0.1%)
OTHER ANTIEMETICS	2 (0.3%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
MECLOZINE	1 (0.1%)	0
PROMETHAZINE	1 (0.1%)	0
SEROTONIN (5HT3) ANTAGONISTS	0	1 (0.1%)
ONDANSETRON	0	1 (0.1%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1%)	2 (0.3%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0.1%)	2 (0.3%)
TRIAMCINOLONE ACETONIDE	0	2 (0.3%)
DESONIDE	1 (0.1%)	0
IMMUNE SERA AND IMMUNOGLOBULINS	3 (0.4%)	0
SPECIFIC IMMUNOGLOBULINS	3 (0.4%)	0
HYPERIMMUNE PLASMA COVID-19	3 (0.4%)	0
ANTINEOPLASTIC AGENTS	2 (0.3%)	0
MONOCLONAL ANTIBODIES	2 (0.3%)	0
RITUXIMAB	2 (0.3%)	0
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	1 (0.1%)	1 (0.1%)
CENTRALLY ACTING ANTIPOBESITY PRODUCTS	1 (0.1%)	1 (0.1%)
PHENTERMINE	1 (0.1%)	1 (0.1%)
OTHER NERVOUS SYSTEM DRUGS	1 (0.1%)	1 (0.1%)
ANTIVERTIGO PREPARATIONS	1 (0.1%)	0
MECLOZINE	1 (0.1%)	0
OTHER NERVOUS SYSTEM DRUGS	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
GABAPENTIN	0	1 (0.1%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	1 (0.1%)	0
OTHER CHEMOTHERAPEUTICS	1 (0.1%)	0
METRONIDAZOLE	1 (0.1%)	0
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1%)	0
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1%)	0
MESALAZINE	1 (0.1%)	0
ANTIFUNGALS FOR DERMATOLOGICAL USE	0	1 (0.1%)
OTHER ANTIFUNGALS FOR TOPICAL USE	0	1 (0.1%)
TOLNAFTATE	0	1 (0.1%)
ANTIMYCOTICS FOR SYSTEMIC USE	1 (0.1%)	0
TRIAZOLE DERIVATIVES	1 (0.1%)	0
FLUCONAZOLE	1 (0.1%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	1 (0.1%)	0
ELECTROLYTE SOLUTIONS	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
DRUGS FOR CONSTIPATION	0	1 (0.1%)
SOFTENERS, EMOLLIENTS	0	1 (0.1%)
DOCUSATE SODIUM	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0.1%)	0
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	1 (0.1%)	0
TRIMEBUTINE	1 (0.1%)	0
DRUGS FOR TREATMENT OF BONE DISEASES	0	1 (0.1%)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	0	1 (0.1%)
DENOSUMAB	0	1 (0.1%)
ENDOCRINE THERAPY	1 (0.1%)	0
ESTROGENS	1 (0.1%)	0
ESTRADIOL	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
IMMUNOSTIMULANTS	1 (0.1%)	0
COLONY STIMULATING FACTORS	1 (0.1%)	0
FILGRASTIM	1 (0.1%)	0
OTHER DERMATOLOGICAL PREPARATIONS	0	1 (0.1%)
OTHER DERMATOLOGICALS	0	1 (0.1%)
FINASTERIDE	0	1 (0.1%)
TONICS	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
TONICS	1 (0.1%)	0
DIETARY SUPPLEMENT	1 (0.1%)	0
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0	1 (0.1%)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	0	1 (0.1%)
DICLOFENAC	0	1 (0.1%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	1 (0.1%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	1 (0.1%)
MITRAGYNA SPECIOSA	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant medication	121 (16.2%)	91 (12.4%)
VITAMINS	45 (6.0%)	31 (4.2%)
VITAMIN D AND ANALOGUES	22 (2.9%)	14 (1.9%)
VITAMIN D NOS	13 (1.7%)	11 (1.5%)
COLECALCIFEROL	9 (1.2%)	3 (0.4%)
ERGOCALCIFEROL	1 (0.1%)	0
ASCORBIC ACID (VITAMIN C), PLAIN	22 (2.9%)	12 (1.6%)
ASCORBIC ACID	22 (2.9%)	12 (1.6%)
MULTIVITAMINS, PLAIN	13 (1.7%)	15 (2.0%)
VITAMINS NOS	12 (1.6%)	15 (2.0%)
ASCORBIC ACID;CALCIUM PANTOTHENATE;COLECALCIFEROL;CYANOCOBALAMIN ;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1 (0.1%)	0
OTHER PLAIN VITAMIN PREPARATIONS	2 (0.3%)	3 (0.4%)
BIOTIN	1 (0.1%)	1 (0.1%)
NICOTINAMIDE	1 (0.1%)	0
TOCOPHERYL ACETATE	0	1 (0.1%)
VITAMIN E NOS	0	1 (0.1%)
MULTIVITAMINS WITH MINERALS	1 (0.1%)	3 (0.4%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
MINERALS NOS;VITAMINS NOS	1 (0.1%)	2 (0.3%)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID;	0	1 (0.1%)
COMBINATIONS OF VITAMINS	2 (0.3%)	0
COLECALCIFEROL;MENAQUINONE-7	1 (0.1%)	0
VITAMINS NOS	1 (0.1%)	0
VITAMIN B-COMPLEX, PLAIN	2 (0.3%)	0
VITAMIN B COMPLEX	2 (0.3%)	0
VITAMINS, OTHER COMBINATIONS	2 (0.3%)	0
ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM;MANGANES E;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	2 (0.3%)	0
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.1%)	0
MINERALS NOS;VITAMINS NOS	1 (0.1%)	0
VITAMIN A AND D IN COMBINATION	1 (0.1%)	0
COD-LIVER OIL	1 (0.1%)	0
VITAMIN A, PLAIN	1 (0.1%)	0
VITAMIN A NOS	1 (0.1%)	0
VITAMIN B1, PLAIN	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
THIAMINE HYDROCHLORIDE	1 (0.1%)	0
VITAMINS WITH MINERALS	1 (0.1%)	0
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID;	1 (0.1%)	0
ANTITHROMBOTIC AGENTS	33 (4.4%)	17 (2.3%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	26 (3.5%)	14 (1.9%)
ACETYLSALICYLIC ACID	25 (3.3%)	14 (1.9%)
CLOPIDOGREL	1 (0.1%)	0
HEPARIN GROUP	7 (0.9%)	1 (0.1%)
ENOXAPARIN SODIUM	5 (0.7%)	0
ENOXAPARIN	2 (0.3%)	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	4 (0.5%)	2 (0.3%)
APIXABAN	3 (0.4%)	1 (0.1%)
RIVAROXABAN	1 (0.1%)	1 (0.1%)
ANALGESICS	13 (1.7%)	19 (2.6%)
ANILIDES	13 (1.7%)	15 (2.0%)
PARACETAMOL	12 (1.6%)	13 (1.8%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRIN E	0	1 (0.1%)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	0	2 (0.3%)
CODEINE PHOSPHATE;PARACETAMOL	0	1 (0.1%)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	0	1 (0.1%)
OTHER ANALGESICS AND ANTIPYRETICS	0	2 (0.3%)
GABAPENTIN	0	2 (0.3%)
OTHER ANTIMIGRAINE PREPARATIONS	0	1 (0.1%)
TOPIRAMATE	0	1 (0.1%)
MINERAL SUPPLEMENTS	18 (2.4%)	14 (1.9%)
ZINC	12 (1.6%)	11 (1.5%)
ZINC	12 (1.6%)	11 (1.5%)
MAGNESIUM	4 (0.5%)	2 (0.3%)
MAGNESIUM	3 (0.4%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
MAGNESIUM CHLORIDE	0	1 (0.1%)
MAGNESIUM CITRATE	0	1 (0.1%)
MAGNESIUM MALATE	0	1 (0.1%)
MAGNESIUM OXIDE	1 (0.1%)	0
CALCIUM	2 (0.3%)	3 (0.4%)
CALCIUM	2 (0.3%)	2 (0.3%)
CALCIUM CARBONATE	0	1 (0.1%)
POTASSIUM	3 (0.4%)	1 (0.1%)
POTASSIUM	2 (0.3%)	1 (0.1%)
POTASSIUM CHLORIDE	1 (0.1%)	0
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	2 (0.3%)	0
CALCIUM CITRATE;COLECALCIFEROL	1 (0.1%)	0
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1%)	0
OTHER MINERAL PRODUCTS	1 (0.1%)	0
STRONTIUM	1 (0.1%)	0
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	13 (1.7%)	16 (2.2%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	9 (1.2%)	8 (1.1%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	4 (0.5%)	1 (0.1%)
ETHINYLESTRADIOL;NORGESTIMATE	2 (0.3%)	3 (0.4%)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	0	3 (0.4%)
DROSPIRENONE;ETHINYLESTRADIOL	1 (0.1%)	1 (0.1%)
DROSPIRENONE;ETHINYLESTRADIOL BETADEX CLATHRATE	1 (0.1%)	0
ETHINYLESTRADIOL;LEVONORGESTREL	1 (0.1%)	0
-OXOANDROSTEN (4) DERIVATIVES	2 (0.3%)	2 (0.3%)
TESTOSTERONE	2 (0.3%)	1 (0.1%)
TESTOSTERONE ENANTHATE	0	1 (0.1%)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0	4 (0.5%)
ESTRADIOL	0	3 (0.4%)
ETHINYLESTRADIOL	0	1 (0.1%)
PROGESTOGENS	0	3 (0.4%)
ETONOGESTREL	0	2 (0.3%)
NORETHISTERONE	0	1 (0.1%)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS	1 (0.1%)	1 (0.1%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	1 (0.1%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
EMERGENCY CONTRACEPTIVES	1 (0.1%)	0
LEVONORGESTREL	1 (0.1%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	8 (1.1%)	6 (0.8%)
PROPIONIC ACID DERIVATIVES	8 (1.1%)	6 (0.8%)
IBUPROFEN	8 (1.1%)	6 (0.8%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	0	1 (0.1%)
DICLOFENAC POTASSIUM	0	1 (0.1%)
LIPID MODIFYING AGENTS	6 (0.8%)	5 (0.7%)
OTHER LIPID MODIFYING AGENTS	4 (0.5%)	3 (0.4%)
FISH OIL	3 (0.4%)	2 (0.3%)
ALIROCUMAB	1 (0.1%)	0
EICOSAPENTAENOIC ACID ETHYL ESTER	0	1 (0.1%)
OMEGA-3 NOS	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS	3 (0.4%)	1 (0.1%)
ATORVASTATIN	1 (0.1%)	1 (0.1%)
ROSUVASTATIN CALCIUM	1 (0.1%)	0
SIMVASTATIN	1 (0.1%)	0
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	0	1 (0.1%)
MONASCUS PURPUREUS	0	1 (0.1%)
ANTIBACTERIALS FOR SYSTEMIC USE	4 (0.5%)	5 (0.7%)
MACROLIDES	2 (0.3%)	3 (0.4%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
AZITHROMYCIN	1 (0.1%)	3 (0.4%)
CLARITHROMYCIN	1 (0.1%)	0
TETRACYCLINES	1 (0.1%)	1 (0.1%)
DOXYCYCLINE	1 (0.1%)	1 (0.1%)
THIRD-GENERATION CEPHALOSPORINS	1 (0.1%)	1 (0.1%)
CEFDINIR	1 (0.1%)	1 (0.1%)
ANTIBACTERIALS FOR SYSTEMIC USE	0	1 (0.1%)
PENICILLIN NOS	0	1 (0.1%)
PSYCHOLEPTICS	4 (0.5%)	5 (0.7%)
BENZODIAZEPINE DERIVATIVES	1 (0.1%)	3 (0.4%)
CLONAZEPAM	1 (0.1%)	2 (0.3%)
ALPRAZOLAM	0	1 (0.1%)
MELATONIN RECEPTOR AGONISTS	2 (0.3%)	2 (0.3%)
MELATONIN	2 (0.3%)	2 (0.3%)
AZASPIRODECANEDIONE DERIVATIVES	1 (0.1%)	0
BUSPIRONE	1 (0.1%)	0
DIPHENYLMETHANE DERIVATIVES	1 (0.1%)	0
HYDROXYZINE	1 (0.1%)	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.5%)	4 (0.5%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.5%)	4 (0.5%)
SAMBUCUS NIGRA	0	2 (0.3%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.1%)	1 (0.1%)
BACOPA MONNIERI	1 (0.1%)	0
CURCUMA LONGA RHIZOME	1 (0.1%)	0
MALUS SPP. VINEGAR EXTRACT	1 (0.1%)	0
PRUNUS CERASUS	1 (0.1%)	0
WITHANIA SOMNIFERA	0	1 (0.1%)
ANTIHISTAMINES FOR SYSTEMIC USE	3 (0.4%)	3 (0.4%)
AMINOALKYL ETHERS	0	2 (0.3%)
CARBINOXAMINE	0	1 (0.1%)
DOXYLAMINE SUCCINATE	0	1 (0.1%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3%)	0
LORATADINE	1 (0.1%)	0
QUERCETIN	1 (0.1%)	0
PIPERAZINE DERIVATIVES	1 (0.1%)	1 (0.1%)
CETIRIZINE	1 (0.1%)	0
CETIRIZINE HYDROCHLORIDE	0	1 (0.1%)
DRUGS FOR ACID RELATED DISORDERS	3 (0.4%)	3 (0.4%)
PROTON PUMP INHIBITORS	2 (0.3%)	3 (0.4%)
OMEPRAZOLE	1 (0.1%)	1 (0.1%)
ESOMEPRAZOLE	0	1 (0.1%)
LANSOPRAZOLE	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
PANTOPRAZOLE	0	1 (0.1%)
H2-RECEPTOR ANTAGONISTS	1 (0.1%)	0
FAMOTIDINE	1 (0.1%)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (0.4%)	3 (0.4%)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	3 (0.4%)	3 (0.4%)
PROBIOTICS NOS	2 (0.3%)	1 (0.1%)
QUERCETIN	1 (0.1%)	2 (0.3%)
CARDIAC THERAPY	3 (0.4%)	2 (0.3%)
OTHER CARDIAC PREPARATIONS	3 (0.4%)	1 (0.1%)
UBIDECARENONE	3 (0.4%)	0
IVABRADINE HYDROCHLORIDE	0	1 (0.1%)
ADRENERGIC AND DOPAMINERGIC AGENTS	0	1 (0.1%)
EPINEPHRINE	0	1 (0.1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3%)	2 (0.3%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	2 (0.3%)	0
SALBUTAMOL	1 (0.1%)	0
SALBUTAMOL SULFATE	1 (0.1%)	0
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	0	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
LEUKOTRIENE RECEPTOR ANTAGONISTS	0	1 (0.1%)
MONTELUKAST	0	1 (0.1%)
ANTIDIARRHEALS, INTESTINAL	3 (0.4%)	0
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
ANTIDIARRHEAL MICROORGANISMS	2 (0.3%)	0
BIFIDOBACTERIUM LACTIS;INULIN;LACTOBACILLUS	1 (0.1%)	0
ACIDOPHILUS;LACTOBACILLUS		
PARACASEI;SACCHAROMYCES		
BOULARDII;TRANS-GALACTOOLIGOSACCHARIDE		
PROBIOTICS NOS	1 (0.1%)	0
ORAL REHYDRATION SALT FORMULATIONS	1 (0.1%)	0
ELECTROLYTES NOS;GLUCOSE	1 (0.1%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	3 (0.4%)	0
ELECTROLYTE SOLUTIONS	2 (0.3%)	0
MAGNESIUM SULFATE	2 (0.3%)	0
POTASSIUM CHLORIDE	1 (0.1%)	0
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM	1 (0.1%)	0
PHOSPHATE MONOBASIC		
SODIUM CHLORIDE	1 (0.1%)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1 (0.1%)	0
POTASSIUM	1 (0.1%)	0
DRUGS FOR CONSTIPATION	3 (0.4%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
OSMOTICALLY ACTING LAXATIVES	2 (0.3%)	0
MAGNESIUM HYDROXIDE	2 (0.3%)	0
LACTULOSE	1 (0.1%)	0
SOFTENERS, EMOLLIENTS	2 (0.3%)	0
DOCUSATE SODIUM	2 (0.3%)	0
CONTACT LAXATIVES	1 (0.1%)	0
BISACODYL	1 (0.1%)	0
PSYCHOANALEPTICS	3 (0.4%)	0
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.1%)	0
ATOMOXETINE	1 (0.1%)	0
OTHER ANTIDEPRESSANTS	1 (0.1%)	0
TRAZODONE	1 (0.1%)	0
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	1 (0.1%)	0
SERTRALINE HYDROCHLORIDE	1 (0.1%)	0
ANTIANEMIC PREPARATIONS	2 (0.3%)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	2 (0.3%)	0
VITAMIN B12 NOS	2 (0.3%)	0
IRON BIVALENT, ORAL PREPARATIONS	1 (0.1%)	0
ASCORBIC ACID;FERROUS FUMARATE	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
ACICLOVIR	0	1 (0.1%)
OTHER ANTIVIRALS	1 (0.1%)	0
THYMALFASIN	1 (0.1%)	0
BETA BLOCKING AGENTS	1 (0.1%)	1 (0.1%)
BETA BLOCKING AGENTS, SELECTIVE	1 (0.1%)	1 (0.1%)
METOPROLOL	1 (0.1%)	1 (0.1%)
COUGH AND COLD PREPARATIONS	1 (0.1%)	1 (0.1%)
EXPECTORANTS	1 (0.1%)	0
GUAIFENESIN	1 (0.1%)	0
MUCOLYTICS	0	1 (0.1%)
ACETYLCYSTEINE	0	1 (0.1%)
ENDOCRINE THERAPY	1 (0.1%)	1 (0.1%)
AROMATASE INHIBITORS	1 (0.1%)	1 (0.1%)
,3'-DIINDOLYLMET HANE	0	1 (0.1%)
LETROZOLE	1 (0.1%)	0
IMMUNOSTIMULANTS	2 (0.3%)	0
HERBAL IMMUNOMODULATORS	2 (0.3%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ASCORBIC ACID;CALCIUM;CORDYCEPS SINENSIS;GANODERMA LUCIDUM;GRIFOLA FRONDOSA;HERICIUM ERINACEUS;VITAMIN D NOS	1 (0.1%)	0
ECHINACEA SPP.	1 (0.1%)	0
OTHER GYNECOLOGICALS	2 (0.3%)	0
INTRAUTERINE CONTRACEPTIVES	2 (0.3%)	0
LEVONORGESTREL	2 (0.3%)	0
OTHER NERVOUS SYSTEM DRUGS	0	2 (0.3%)
DRUGS USED IN OPIOID DEPENDENCE	0	1 (0.1%)
NALTREXONE	0	1 (0.1%)
OTHER PARASYMPATHOMIMETICS	0	1 (0.1%)
CEVIMELINE	0	1 (0.1%)
Uncoded	2 (0.3%)	0
Uncoded	2 (0.3%)	0
Uncoded	2 (0.3%)	0
VACCINES	1 (0.1%)	1 (0.1%)
INFLUENZA VACCINES	0	1 (0.1%)
INFLUENZA VACCINE	0	1 (0.1%)
OTHER VIRAL VACCINES	1 (0.1%)	0
COVID-19 VACCINE	1 (0.1%)	0
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1%)	0
LOSARTAN	1 (0.1%)	0
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ASCORBIC ACID	0	1 (0.1%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.1%)	0
MEDICAL GASES	1 (0.1%)	0
OXYGEN	1 (0.1%)	0
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	1 (0.1%)	0
OTHER ANTIBIOTICS FOR TOPICAL USE	1 (0.1%)	0
BACITRACIN	1 (0.1%)	0
ANTIEMETICS AND ANTINAUSEANTS	0	1 (0.1%)
OTHER ANTIEMETICS	0	1 (0.1%)
PROMETHAZINE	0	1 (0.1%)
ANTIHYPERTENSIVES	0	1 (0.1%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	0	1 (0.1%)
PRAZOSIN	0	1 (0.1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	1 (0.1%)	0
CENTRALLY ACTING ANTIOBESITY PRODUCTS	1 (0.1%)	0
PHENTERMINE	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
CORTICOSTEROIDS FOR SYSTEMIC USE	0	1 (0.1%)
GLUCOCORTICIDS	0	1 (0.1%)
BECLOMETASONE	0	1 (0.1%)
EMOLLIENTS AND PROTECTIVES	1 (0.1%)	0
ZINC PRODUCTS	1 (0.1%)	0
MENTHOL;ZINC OXIDE	1 (0.1%)	0
NASAL PREPARATIONS	0	1 (0.1%)
OTHER NASAL PREPARATIONS	0	1 (0.1%)
SODIUM CHLORIDE;XYLITOL	0	1 (0.1%)
OPHTHALMOLOGICALS	1 (0.1%)	0
OTHER OPHTHALMOLOGICALS	1 (0.1%)	0
CARMELLOSE	1 (0.1%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.1%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.1%)	0
AMINO ACIDS NOS;ANIMAL UNSPECIFIED;ASCORBIC ACID;CYANOCOBALAMIN;HERBAL NOS;MANGANESE;PHOSPHORUS;RETINOL PALMITATE;TOCOPHEROL	1 (0.1%)	0
UROLOGICALS	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.4. Concomitant medications day 1 to day 29
Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
DRUGS USED IN ERECTILE DYSFUNCTION	1 (0.1%)	0
SILDENAFIL	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant medication	3 (0.4%)	12 (1.6%)
ANTITHROMBOTIC AGENTS	1 (0.1%)	8 (1.1%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	1 (0.1%)	8 (1.1%)
ACETYLSALICYLIC ACID	1 (0.1%)	7 (1.0%)
CLOPIDOGREL	0	1 (0.1%)
CLOPIDOGREL BISULFATE	0	1 (0.1%)
VITAMINS	0	3 (0.4%)
VITAMIN D AND ANALOGUES	0	2 (0.3%)
COLECALCIFEROL	0	1 (0.1%)
VITAMIN D NOS	0	1 (0.1%)
ASCORBIC ACID (VITAMIN C), PLAIN	0	1 (0.1%)
ASCORBIC ACID	0	1 (0.1%)
MULTIVITAMINS, PLAIN	0	1 (0.1%)
VITAMINS NOS	0	1 (0.1%)
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	1 (0.1%)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1%)	1 (0.1%)
EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	1 (0.1%)	1 (0.1%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
VALACICLOVIR HYDROCHLORIDE	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
ANTIGOUT PREPARATIONS	0	1 (0.1%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	0	1 (0.1%)
ALLOPURINOL	0	1 (0.1%)
LIPID MODIFYING AGENTS	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS	0	1 (0.1%)
SIMVASTATIN	0	1 (0.1%)
OTHER GYNECOLOGICALS	1 (0.1%)	0
INTRAVAGINAL CONTRACEPTIVES	1 (0.1%)	0
ETHINYLESTRADIOL;ETONOGESTREL	1 (0.1%)	0
PSYCHOANALEPTICS	1 (0.1%)	0
OTHER ANTIDEPRESSANTS	1 (0.1%)	0
LAMOTRIGINE	1 (0.1%)	0
VENLAFAXINE HYDROCHLORIDE	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 22.1. Concomitant procedures day 1 to day 29
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant procedure	51 (6.8%)	31 (4.2%)
Investigations	50 (6.7%)	27 (3.7%)
Physical examination	37 (4.9%)	23 (3.1%)
Chest X-ray	11 (1.5%)	2 (0.3%)
Viral test	4 (0.5%)	3 (0.4%)
Electrocardiogram	2 (0.3%)	2 (0.3%)
Angiogram	3 (0.4%)	0
Ultrasound Doppler	3 (0.4%)	0
Computerised tomogram thorax	2 (0.3%)	0
Abdominal X-ray	1 (0.1%)	0
Computerised tomogram	0	1 (0.1%)
Computerised tomogram abdomen	1 (0.1%)	0
Echocardiogram	1 (0.1%)	0
X-ray	0	1 (0.1%)
X-ray gastrointestinal tract	1 (0.1%)	0
X-ray with contrast upper gastrointestinal tract	1 (0.1%)	0
Surgical and medical procedures	4 (0.5%)	6 (0.8%)
Mechanical ventilation	1 (0.1%)	1 (0.1%)
Angioplasty	0	1 (0.1%)
Arterial catheterisation	1 (0.1%)	0
Bilevel positive airway pressure	1 (0.1%)	0
Cautery to nose	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 22.1. Concomitant procedures day 1 to day 29
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Central venous catheterisation	1 (0.1%)	0
Chemical peel of skin	0	1 (0.1%)
Cholecystectomy	1 (0.1%)	0
Coronary arterial stent insertion	0	1 (0.1%)
Dialysis	1 (0.1%)	0
Endotracheal intubation	1 (0.1%)	0
Enterorrhaphy	1 (0.1%)	0
Explorative laparotomy	1 (0.1%)	0
Eye operation	0	1 (0.1%)
Gastrointestinal tube insertion	1 (0.1%)	0
Incisional drainage	0	1 (0.1%)
Physiotherapy	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 22.2. Concomitant procedures day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant procedure	3 (0.4%)	0
Investigations	3 (0.4%)	0
Chest X-ray	2 (0.3%)	0
Angiogram	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 22.3. Concomitant procedures day 1 to day 29
Indication Reason: Adverse Event
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant procedure	12 (1.6%)	6 (0.8%)
Investigations	11 (1.5%)	4 (0.5%)
Chest X-ray	9 (1.2%)	2 (0.3%)
Electrocardiogram	2 (0.3%)	2 (0.3%)
Ultrasound Doppler	3 (0.4%)	0
Angiogram	2 (0.3%)	0
Computerised tomogram thorax	2 (0.3%)	0
Abdominal X-ray	1 (0.1%)	0
Computerised tomogram	0	1 (0.1%)
Computerised tomogram abdomen	1 (0.1%)	0
Echocardiogram	1 (0.1%)	0
Physical examination	1 (0.1%)	0
X-ray	0	1 (0.1%)
X-ray gastrointestinal tract	1 (0.1%)	0
X-ray with contrast upper gastrointestinal tract	1 (0.1%)	0
Surgical and medical procedures	4 (0.5%)	3 (0.4%)
Mechanical ventilation	1 (0.1%)	1 (0.1%)
Angioplasty	0	1 (0.1%)
Arterial catheterisation	1 (0.1%)	0
Bilevel positive airway pressure	1 (0.1%)	0
Cautery to nose	1 (0.1%)	0
Central venous catheterisation	1 (0.1%)	0

Clinical cut-off: 18Feb2021

Table 22.3. Concomitant procedures day 1 to day 29
Indication Reason: Adverse Event
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Cholecystectomy	1 (0.1%)	0
Coronary arterial stent insertion	0	1 (0.1%)
Dialysis	1 (0.1%)	0
Endotracheal intubation	1 (0.1%)	0
Enterorrhaphy	1 (0.1%)	0
Explorative laparotomy	1 (0.1%)	0
Gastrointestinal tube insertion	1 (0.1%)	0
Incisional drainage	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 22.4. Concomitant procedures day 1 to day 29
Indication Reason: Disease under study
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant procedure	37 (4.9%)	22 (3.0%)
Investigations	37 (4.9%)	21 (2.9%)
Physical examination	37 (4.9%)	21 (2.9%)
Viral test	4 (0.5%)	3 (0.4%)
Surgical and medical procedures	0	1 (0.1%)
Physiotherapy	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 22.5. Concomitant procedures day 1 to day 29
Indication Reason: Other
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=748)	Casirivimab/Imdevimab (N=736)
Subjects with at least one concomitant procedure	1 (0.1%)	4 (0.5%)
Investigations	1 (0.1%)	2 (0.3%)
Physical examination	0	2 (0.3%)
Ultrasound Doppler	1 (0.1%)	0
Surgical and medical procedures	0	2 (0.3%)
Chemical peel of skin	0	1 (0.1%)
Eye operation	0	1 (0.1%)

Clinical cut-off: 18Feb2021

Table 27: Frequency of Baseline Risk Factors for Severe COVID-19 (Phase 3, mFAS)

	Placebo		REGN10933+REGN10987			Total (N=4057)
	Pooled for 1200 mg IV analysis ¹ (N=748)	Pooled for 2400 mg IV analysis ¹ (N=1341)	1200 mg IV (N=736)	2400 mg IV (N=1355)	8000 mg IV (N=625)	
<i>Risk factor for Severe COVID-19</i>						
Age ≥50 years	356 (47.6%)	678 (50.6%)	357 (48.5%)	715 (52.8%)	351 (56.2%)	2101 (51.8%)
Obesity, defined as BMI ≥30 kg/m ²	427 (57.1%)	772 (57.6%)	410 (55.7%)	787 (58.1%)	384 (61.4%)	2353 (58.0%)
Cardiovascular disease, including hypertension	266 (35.6%)	473 (35.3%)	282 (38.3%)	520 (38.4%)	196 (31.4%)	1471 (36.3%)
Chronic lung disease, including asthma	139 (18.6%)	219 (16.3%)	139 (18.9%)	216 (15.9%)	92 (14.7%)	666 (16.4%)
Type 1 or type 2 diabetes mellitus	100 (13.4%)	210 (15.7%)	94 (12.8%)	202 (14.9%)	97 (15.5%)	603 (14.9%)
Chronic kidney disease, including those on dialysis	4 (0.5%)	9 (0.7%)	8 (1.1%)	19 (1.4%)	9 (1.4%)	45 (1.1%)
Chronic liver disease	4 (0.5%)	8 (0.6%)	3 (0.4%)	14 (1.0%)	11 (1.8%)	36 (0.9%)
Immunocompromised	10 (1.3%)	34 (2.5%)	24 (3.3%)	46 (3.4%)	16 (2.6%)	120 (3.0%)
Immunosuppressed	10 (1.3%)	31 (2.3%)	24 (3.3%)	46 (3.4%)	15 (2.4%)	116 (2.9%)
Taking Immunosuppressants	0	11 (0.8%)	0	10 (0.7%)	6 (1.0%)	27 (0.7%)

¹Placebo is presented in two columns, based on those that were concurrently randomized to the 1200 mg and 2400 mg active treatment groups. The placebo group marked as "pooled for 1200 mg IV analysis" is a subset of the placebo group marked as "pooled for 2400 mg IV analysis."

Source: Phase 3 PTTs 14.1.2.5.1M, 14.1.2.5.1M.1

EXECUTIVE SUMMARY*

At the onset of the COVID-19 global emergency, there was limited understanding of what constituted disease progression in COVID-19 and how the symptoms experienced by patients manifested themselves and/or impacted their lives. With limited availability of data and of COVID-19 specific regulatory guidance, Regeneron embraced the Food and Drug Administration (FDA)'s Roadmap to Patient-Focused Outcomes Measurement in Clinical Trials (FDA, 2015) to characterize the COVID-19 patient experience that, in turn, would enable conceptualization of treatment benefit, and thus inform patient-centered outcome measures and endpoints in casirivimab+imdevimab clinical development studies. Further, while there were existing measures such as the InFLUenza Patient-Reported Outcome (FLUPRO), there was no fit-for-purpose disease-specific instrument for COVID-19 for use in Regeneron's target population. Consequently, Regeneron developed and validated a new patient-reported outcomes (PRO) electronic diary, specifically focused on symptoms to gain insight into symptoms evolution in ambulatory patients with COVID-19. This work was initiated several months prior to the release of the FDA COVID-19 guidance on Assessing Symptoms in Outpatient Adults and Adolescents (FDA, 2020a).

The Symptoms Evolution of COVID-19 Instrument (SE-C19) was developed initially based on the Centers for Disease Control and Prevention (CDC) COVID symptom list (CDC, 2021) and available published literature specific to patients with COVID-19 (Michelen et al., 2020). The SE-C19 includes a list of 23 symptoms: fever, chills, sore throat, cough, shortness of breath or difficulty breathing, nausea, vomiting, diarrhea, headache, red or watery eyes, body aches such as muscle pain and joint pain, loss of taste or smell, fatigue, loss of appetite, confusion, dizziness, pressure or tightness in chest, chest pain, stomach-ache, rash, sneezing, sputum/phlegm, and runny nose. The good measurement principles outlined in the FDA PRO Guidance (FDA, 2009) and the four methodological Patient-Focused Drug Development Guidances (FDA, 2018, 2019a, 2019b, 2020b) were applied during the further development and evaluation of the instrument.

The content validity of the instrument was primarily demonstrated through interviews with patients that included an open-ended portion (concept elicitation) about their experience with COVID-19, and also asking them to respond and comment on the items themselves (cognitive debriefing). The concept elicitation established that the 23 items covered the most important and relevant symptoms for patients, confirming that no additional items were needed to capture the patient's experience of COVID-19. The patient interviews also confirmed that patients understood and could complete the items (with the exception of 'sputum/phlegm', which was not clear to some patients). Interviews with clinicians confirmed the patient perspectives, further establishing content validity.

Psychometric analyses of the SE-C19 were conducted on the blinded data from the Phase 1/2 trial and confirmed in the Phase 3 trial. All analyses were prespecified in independent analysis plans and were finalized prior to the database lock of both trials. These analyses demonstrated generally acceptable levels of test-retest reliability for the individual SE-C19 items, good known groups validity, responsiveness.

SE-C19

The collective empirical evidence from patients/clinician interviews as well as classical and modern psychometrics analyses provided support for the SE-C19 and its scoring. More specifically: 1) The psychometric analyses evaluating the performance of individual items suggested the removal of four items from any endpoint construction: vomiting, confusion, rash, and sneezing; 2) the analysis of the distribution of items response over time, ability to detect change, and known groups comparison has provided empirical evidence to support the observation that some symptoms may resolve at a slower rate than others during the course of the COVID-19 illness. We found that cough, headache, and fatigue were persistent over time, even though they showed sensitivity to change. These results suggest that when developing a time-to-resolution endpoint, it is pertinent to consider the different time scales of the resolution of those symptoms. Thus, any resolution of cough, fatigue and headache symptoms in this context of use would be most appropriate if patients experience ‘none’ or at most ‘mild/moderate’ levels; 3) finally, the Rasch analysis suggested that subjects were not able to differentiate between mild and moderate symptoms and as a result a modified symptom severity rating scale that collapses the mild/moderate categories was found to be most appropriate;

In infectious disease a successful treatment outcome is a complete resolution of symptoms (e.g., FDA 2011 on treatment of flu). As such, an endpoint based on the SE-C19 defines patients into responders and non-responders, where responders exhibit resolution of a specific set of symptoms at a certain point in time. In study COV-2067, a key secondary endpoint was the time to sustained COVID-19 resolution of symptoms for at least 1 day, as measured by the SE-C19 in a trial-specific daily symptom diary. Time to COVID-19 resolution of symptoms was defined as time from randomization to the first day during which the subject scored ‘no symptom’ (score of 0) on 16 symptoms, and ‘mild/moderate’ (score of 1) or ‘no symptom’ (score of 0) on 3 symptoms.

It is Regeneron’s position that the SE-C19 is fit for purpose for use as the basis of the key secondary symptom endpoint for study COV-2067 and appropriate to support a PRO labeling claim based upon the significant and clinically meaningful results.

*This executive summary is an excerpt of the "Patient-Reported Outcomes (PRO) Evidence Dossier: The Symptoms Evolution of Covid-19 (SE-C19) Instrument"

For any questions related to the SE-C19 development, modifications, validation, adaption or use; please contact:

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Datenschnitt 18.02.2021 (DCO1)

Verträglichkeit

Hauptdokumente

POPULATION: Safety
 ENDPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference		Relative Risk			Relative Risk			Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	827	100	59	7.1	828	100	79	9.5	0.73	Algorithm converged.	0.51	1.04	-2.407	Algorithm converged.	-5.07	0.25	0.75	Algorithm converged.	0.54	1.03	0.0767		1.34	Algorithm converged.	0.97	1.85
Sex	Male	405	49	29	7.2	381	46	41	10.8	0.64	Algorithm converged.	0.39	1.05	-3.601	Algorithm converged.	-7.6	0.4	0.67	Algorithm converged.	0.42	1.05	0.0767	0.4884	1.5	Algorithm converged.	0.95	2.37
	Female	422	51	30	7.1	447	54	38	8.5	0.82	Algorithm converged.	0.5	1.36	-1.392	Algorithm converged.	-4.96	2.17	0.84	Algorithm converged.	0.53	1.32	0.4453		1.2	Algorithm converged.	0.76	1.89
Age	18-64	724	87.5	47	6.5	737	89	62	8.4	0.76	Algorithm converged.	0.51	1.12	-1.921	Algorithm converged.	-4.61	0.77	0.77	Algorithm converged.	0.54	1.11	0.1626	0.7925	1.3	Algorithm converged.	0.9	1.87
	65-74	70	8.5	9	12.9	70	8.5	13	18.6	0.65	Algorithm converged.	0.26	1.63	-5.714	Algorithm converged.	-17.73	6.31	0.69	Algorithm converged.	0.32	1.51	0.3547		1.44	Algorithm converged.	0.66	3.16
	>=75	33	4	3	9.1	21	2.5	4	19	0.43	Algorithm converged.	0.08	2.13	-9.957	Algorithm converged.	-29.41	9.49	0.48	Algorithm converged.	0.12	1.92	0.4113		2.1	Algorithm converged.	0.52	8.44
Baseline viral load categories	<=10 ⁵ copies/mL	210	25.4	13	6.2	209	25.2	11	5.3	1.19	Algorithm converged.	0.52	2.72	0.927	Algorithm converged.	-3.52	5.38	1.18	Algorithm converged.	0.54	2.57	0.6833	0.1144	0.85	Algorithm converged.	0.39	1.85
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.9	4	4.4	123	14.9	9	7.3	0.59	Algorithm converged.	0.18	1.98	-2.873	Algorithm converged.	-9.14	3.4	0.61	Algorithm converged.	0.19	1.91	0.5642		1.65	Algorithm converged.	0.52	5.18
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.4	5	4.2	125	15.1	18	14.4	0.26	Algorithm converged.	0.09	0.73	-10.198	Algorithm converged.	-17.33	-3.07	0.29	Algorithm converged.	0.11	0.76	0.0078		3.43	Algorithm converged.	1.31	8.94
	>10 ⁷ copies/mL	363	43.9	34	9.4	346	41.8	40	11.6	0.79	Algorithm converged.	0.49	1.28	-2.194	Algorithm converged.	-6.7	2.32	0.81	Algorithm converged.	0.53	1.25	0.3398		1.23	Algorithm converged.	0.8	1.9
	Unknown	45	5.4	3	6.7	25	3	1	4	1.71	Algorithm converged.	0.17	17.41	2.667	Algorithm converged.	-7.92	13.26	1.67	Algorithm converged.	0.18	15.19	1		0.6	Algorithm converged.	0.07	5.47
Country	USA	785	94.9	57	7.3	787	95	76	9.7	0.73	Algorithm converged.	0.51	1.05	-2.396	Algorithm converged.	-5.14	0.35	0.75	Algorithm converged.	0.54	1.04	0.088	0.8722	1.33	Algorithm converged.	0.96	1.85
	MEX	42	5.1	2	4.8	41	5	3	7.3	0.63	Algorithm converged.	0.1	4	-2.555	Algorithm converged.	-12.8	7.69	0.65	Algorithm converged.	0.11	3.7	0.6758		1.54	Algorithm converged.	0.27	8.73

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-1-ae-raw-anyae

POPULATION: Safety
 ENDPOINT: Any AEs (excluding disease related events)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference		Relative Risk					Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	827	100	54	6.5	828	100	63	7.6	0.85	Algorithm converged.	0.58	1.24	-1.079	Algorithm converged.	-3.55	1.39	0.86	Algorithm converged.	0.6	1.22	0.392		1.17	Algorithm converged.	0.82	1.65
Sex	Male	405	49	28	6.9	381	46	31	8.1	0.84	Algorithm converged.	0.49	1.43	-1.223	Algorithm converged.	-4.92	2.47	0.85	Algorithm converged.	0.52	1.39	0.5158	0.9715	1.18	Algorithm converged.	0.72	1.92
	Female	422	51	26	6.2	447	54	32	7.2	0.85	Algorithm converged.	0.5	1.45	-0.998	Algorithm converged.	-4.31	2.32	0.86	Algorithm converged.	0.52	1.42	0.5561		1.16	Algorithm converged.	0.7	1.92
Age	18-64	724	87.5	45	6.2	737	89	49	6.6	0.93	Algorithm converged.	0.61	1.41	-0.433	Algorithm converged.	-2.95	2.08	0.93	Algorithm converged.	0.63	1.38	0.7359	0.1784	1.07	Algorithm converged.	0.72	1.58
	65-74	70	8.5	8	11.4	70	8.5	10	14.3	0.77	Algorithm converged.	0.29	2.09	-2.857	Algorithm converged.	-13.94	8.22	0.8	Algorithm converged.	0.34	1.91	0.6148		1.25	Algorithm converged.	0.52	2.98
	>=75	33	4	1	3	21	2.5	4	19	0.13	Algorithm converged.	0.01	1.28	-16.017	Algorithm converged.	-33.8	1.77	0.16	Algorithm converged.	0.02	1.33	0.0689		6.29	Algorithm converged.	0.75	52.47
Baseline viral load categories	<=10 ⁵ copies/mL	210	25.4	12	5.7	209	25.2	9	4.3	1.35	Algorithm converged.	0.56	3.27	1.408	Algorithm converged.	-2.77	5.58	1.33	Algorithm converged.	0.57	3.08	0.5095	0.0512	0.75	Algorithm converged.	0.32	1.75
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.9	3	3.3	123	14.9	7	5.7	0.57	Algorithm converged.	0.14	2.27	-2.358	Algorithm converged.	-7.88	3.17	0.59	Algorithm converged.	0.16	2.2	0.5238		1.71	Algorithm converged.	0.45	6.42
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.4	4	3.4	125	15.1	16	12.8	0.24	Algorithm converged.	0.08	0.73	-9.439	Algorithm converged.	-16.13	-2.75	0.26	Algorithm converged.	0.09	0.76	0.0091		3.81	Algorithm converged.	1.31	11.06
	>10 ⁷ copies/mL	363	43.9	32	8.8	346	41.8	30	8.7	1.02	Algorithm converged.	0.6	1.72	0.145	Algorithm converged.	-4.01	4.3	1.02	Algorithm converged.	0.63	1.64	0.9456		0.98	Algorithm converged.	0.61	1.58
	Unknown	45	5.4	3	6.7	25	3	1	4	1.71	Algorithm converged.	0.17	17.41	2.667	Algorithm converged.	-7.92	13.26	1.67	Algorithm converged.	0.18	15.19	1		0.6	Algorithm converged.	0.07	5.47
Country	USA	785	94.9	52	6.6	787	95	62	7.9	0.83	Algorithm converged.	0.57	1.22	-1.254	Algorithm converged.	-3.82	1.31	0.84	Algorithm converged.	0.59	1.2	0.338	0.4745	1.19	Algorithm converged.	0.83	1.7
	MEX	42	5.1	2	4.8	41	5	1	2.4	2	Algorithm converged.	0.17	22.95	2.323	Algorithm converged.	-5.66	10.31	1.95	Algorithm converged.	0.18	20.71	1		0.51	Algorithm converged.	0.05	5.43

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-2-ae-raw-anyaenr

POPULATION: Safety
 ENDPOINT: AEs grade >= 3
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk												
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	827	100	12	1.5	828	100	25	3	0.47				Algorithm converged.	0.24	0.95	-1.568	Algorithm converged.	-2.99	-0.15	0.48	Algorithm converged.	0.24	0.95	0.031		2.08	Algorithm converged.	1.05	4.11
Sex	Male	405	49	7	1.7	381	46	14	3.7	0.46				Algorithm converged.	0.18	1.15	-1.946	Algorithm converged.	-4.22	0.33	0.47	Algorithm converged.	0.19	1.15	0.091	0.9736	2.13	Algorithm converged.	0.87	5.21
	Female	422	51	5	1.2	447	54	11	2.5	0.48				Algorithm converged.	0.16	1.38	-1.276	Algorithm converged.	-3.04	0.49	0.48	Algorithm converged.	0.17	1.37	0.2089		2.08	Algorithm converged.	0.73	5.93
Age	18-64	724	87.5	9	1.2	737	89	16	2.2	0.57				Algorithm converged.	0.25	1.29	-0.928	Algorithm converged.	-2.25	0.4	0.57	Algorithm converged.	0.25	1.29	0.1717	0.678	1.75	Algorithm converged.	0.78	3.93
	65-74	70	8.5	2	2.9	70	8.5	7	10	0.26				Algorithm converged.	0.05	1.32	-7.143	Algorithm converged.	-15.18	0.9	0.29	Algorithm converged.	0.06	1.33	0.1654		3.5	Algorithm converged.	0.75	16.26
	>=75	33	4	1	3	21	2.5	2	9.5	0.3				Algorithm converged.	0.03	3.5	-6.494	Algorithm converged.	-20.34	7.36	0.32	Algorithm converged.	0.03	3.29	0.553		3.14	Algorithm converged.	0.3	32.54
Baseline viral load categories	<=10 ⁵ copies/mL	210	25.4	3	1.4	209	25.2	1	0.5	3.01				Algorithm converged.	0.31	29.22	0.95	Algorithm converged.	-0.91	2.81	2.99	Algorithm converged.	0.31	28.47	0.6232	0.1045	0.33	Algorithm converged.	0.04	3.19
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.9	0	0	123	14.9	4	3.3	0				Algorithm converged.	NE	NE	-3.252	Algorithm converged.	-6.39	-0.12	NE	Algorithm not converged.	NE	NE	0.1395		NE	Algorithm not converged.	NE	NE
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.4	1	0.8	125	15.1	5	4	0.2				Algorithm converged.	0.02	1.77	-3.16	Algorithm converged.	-6.97	0.65	0.21	Algorithm converged.	0.02	1.77	0.2138		4.76	Algorithm converged.	0.56	40.15
	>10 ⁷ copies/mL	363	43.9	7	1.9	346	41.8	15	4.3	0.43				Algorithm converged.	0.17	1.08	-2.407	Algorithm converged.	-4.98	0.16	0.44	Algorithm converged.	0.18	1.08	0.0649		2.25	Algorithm converged.	0.93	5.45
	Unknown	45	5.4	1	2.2	25	3	0	0	NE	*			Algorithm not converged.	NE	NE	2.222	Algorithm converged.	-2.08	6.53	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Country	USA	785	94.9	12	1.5	787	95	22	2.8	0.54				Algorithm converged.	0.27	1.1	-1.267	Algorithm converged.	-2.7	0.17	0.55	Algorithm converged.	0.27	1.1	0.0844	0.1082	1.83	Algorithm converged.	0.91	3.67
	MEX	42	5.1	0	0	41	5	3	7.3	0				Algorithm converged.	NE	NE	-7.317	Algorithm converged.	-15.29	0.65	NE	Algorithm not converged.	NE	NE	0.116		NE	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-3-ae-raw-toxgrt3

POPULATION: Safety
 ENDPOINT: AEs Grade >= 3 (excluding disease related events)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab		Placebo		Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab															
		Patients		Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
		n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	827	100	11	1.3	828	100	17	2.1	0.64	Algorithm converged.	0.3	1.38	-0.723	Algorithm converged.	-1.97	0.52	0.65	Algorithm converged.	0.31	1.37	0.2543		1.54	Algorithm converged.	0.73	3.28
Sex	Male	405	49	6	1.5	381	46	9	2.4	0.62	Algorithm converged.	0.22	1.76	-0.881	Algorithm converged.	-2.81	1.05	0.63	Algorithm converged.	0.23	1.75	0.3674	0.944	1.59	Algorithm converged.	0.57	4.44
	Female	422	51	5	1.2	447	54	8	1.8	0.66	Algorithm converged.	0.21	2.03	-0.605	Algorithm converged.	-2.21	1	0.66	Algorithm converged.	0.22	2.01	0.5802		1.51	Algorithm converged.	0.5	4.58
Age	18-64	724	87.5	9	1.2	737	89	11	1.5	0.83	Algorithm converged.	0.34	2.02	-0.249	Algorithm converged.	-1.44	0.94	0.83	Algorithm converged.	0.35	2	0.6817	0.4571	1.2	Algorithm converged.	0.5	2.88
	65-74	70	8.5	1	1.4	70	8.5	4	5.7	0.24	Algorithm converged.	0.03	2.2	-4.286	Algorithm converged.	-10.39	1.82	0.25	Algorithm converged.	0.03	2.18	0.3659		4	Algorithm converged.	0.46	34.9
	>=75	33	4	1	3	21	2.5	2	9.5	0.3	Algorithm converged.	0.03	3.5	-6.494	Algorithm converged.	-20.34	7.36	0.32	Algorithm converged.	0.03	3.29	0.553		3.14	Algorithm converged.	0.3	32.54
Baseline viral load categories	<=10^5 copies/mL	210	25.4	3	1.4	209	25.2	0	0	NE *	Algorithm not converged.	NE	NE	1.429	Algorithm converged.	-0.18	3.03	NE *	Algorithm not converged.	NE	NE	0.2482	0.0381	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	90	10.9	0	0	123	14.9	3	2.4	0	Algorithm converged.	NE	NE	-2.439	Algorithm converged.	-5.17	0.29	NE *	Algorithm not converged.	NE	NE	0.2645		NE *	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	14.4	1	0.8	125	15.1	3	2.4	0.34	Algorithm converged.	0.04	3.36	-1.56	Algorithm converged.	-4.7	1.58	0.35	Algorithm converged.	0.04	3.32	0.6224		2.86	Algorithm converged.	0.3	27.08
	>10^7 copies/mL	363	43.9	6	1.7	346	41.8	11	3.2	0.51	Algorithm converged.	0.19	1.4	-1.526	Algorithm converged.	-3.79	0.74	0.52	Algorithm converged.	0.19	1.39	0.1845		1.92	Algorithm converged.	0.72	5.14
	Unknown	45	5.4	1	2.2	25	3	0	0	NE *	Algorithm not converged.	NE	NE	2.222	Algorithm converged.	-2.08	6.53	NE *	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
Country	USA	785	94.9	11	1.4	787	95	17	2.2	0.64	Algorithm converged.	0.3	1.38	-0.759	Algorithm converged.	-2.07	0.55	0.65	Algorithm converged.	0.31	1.38	0.2555	1	1.54	Algorithm converged.	0.73	3.27
	MEX	42	5.1	0	0	41	5	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-4-ae-raw-toxigr3

POPULATION: Safety
 ENDPOINT: AEs grade 3
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	827	100	10	1.2	828	100	21	2.5	0.47	Algorithm converged.	0,22	1,01	-1,327	Algorithm converged.	-2,63	-0,02	0,48	Algorithm converged.	0,23	1,01	0,0465		2,1	Algorithm converged.	0,99	4,43
Sex	Male	405	49	5	1,2	381	46	13	3,4	0,35	Algorithm converged.	0,12	1	-2,178	Algorithm converged.	-4,29	-0,06	0,36	Algorithm converged.	0,13	1,01	0,0549	0,4324	2,76	Algorithm converged.	0,99	7,68
	Female	422	51	5	1,2	447	54	8	1,8	0,66	Algorithm converged.	0,21	2,03	-0,605	Algorithm converged.	-2,21	1	0,66	Algorithm converged.	0,22	2,01	0,5802		1,51	Algorithm converged.	0,5	4,58
Age	18-64	724	87,5	7	1	737	89	12	1,6	0,59	Algorithm converged.	0,23	1,51	-0,661	Algorithm converged.	-1,82	0,5	0,59	Algorithm converged.	0,24	1,5	0,2648	0,6744	1,68	Algorithm converged.	0,67	4,25
	65-74	70	8,5	2	2,9	70	8,5	7	10	0,26	Algorithm converged.	0,05	1,32	-7,143	Algorithm converged.	-15,18	0,9	0,29	Algorithm converged.	0,06	1,33	0,1654		3,5	Algorithm converged.	0,75	16,26
	>=75	33	4	1	3	21	2,5	2	9,5	0,3	Algorithm converged.	0,03	3,5	-6,494	Algorithm converged.	-20,34	7,36	0,32	Algorithm converged.	0,03	3,29	0,553		3,14	Algorithm converged.	0,3	32,54
Baseline viral load categories	<=10^5 copies/mL	210	25,4	2	1	209	25,2	1	0,5	2	Algorithm converged.	0,18	22,23	0,474	Algorithm converged.	-1,14	2,09	1,99	Algorithm converged.	0,18	21,78	1	0,14	0,5	Algorithm converged.	0,05	5,5
	>10^5 copies/mL - <=10^6 copies/mL	90	10,9	0	0	123	14,9	3	2,4	0	Algorithm converged.	NE	NE	-2,439	Algorithm converged.	-5,17	0,29	NE	Algorithm not converged.	NE	NE	0,2645		NE	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	14,4	0	0	125	15,1	3	2,4	0	Algorithm converged.	NE	NE	-2,4	Algorithm converged.	-5,08	0,28	NE	Algorithm not converged.	NE	NE	0,2474		NE	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	43,9	7	1,9	346	41,8	14	4	0,47	Algorithm converged.	0,19	1,17	-2,118	Algorithm converged.	-4,63	0,39	0,48	Algorithm converged.	0,19	1,17	0,0966		2,1	Algorithm converged.	0,86	5,14
	Unknown	45	5,4	1	2,2	25	3	0	0	NE	*	Algorithm not converged.	NE	NE	2,222	Algorithm converged.	-2,08	6,53	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE
Country	USA	785	94,9	10	1,3	787	95	19	2,4	0,52	Algorithm converged.	0,24	1,13	-1,14	Algorithm converged.	-2,47	0,19	0,53	Algorithm converged.	0,25	1,13	0,0931	0,195	1,9	Algorithm converged.	0,89	4,05
	MEX	42	5,1	0	0	41	5	2	4,9	0	Algorithm converged.	NE	NE	-4,878	Algorithm converged.	-11,47	1,72	NE	Algorithm not converged.	NE	NE	0,241		NE	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-5-ae-raw-toxgr3

POPULATION: Safety
 ENDPOINT: AEs grade 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference		Relative Risk			Relative Risk			Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	827	100	1	0,1	828	100	3	0,4	0,33	Algorithm converged.	0,03	3,21	-0,241	Algorithm converged.	-0,71	0,23	0,33	Algorithm converged.	0,03	3,2	0,6245		3	Algorithm converged.	0,31	28,75		
Sex	Male	405	49	1	0,2	381	46	1	0,3	0,94	Algorithm converged.	0,06	15,09	-0,016	Algorithm converged.	-0,72	0,69	0,94	Algorithm converged.	0,06	14,99	1	0,2042	1,06	Algorithm converged.	0,07	16,93		
	Female	422	51	0	0	447	54	2	0,4	0	Algorithm converged.	NE	NE	-0,447	Algorithm converged.	-1,07	0,17	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	*	Algorithm not converged.	NE	NE
Age	18-64	724	87,5	1	0,1	737	89	3	0,4	0,34	Algorithm converged.	0,04	3,26	-0,269	Algorithm converged.	-0,8	0,26	0,34	Algorithm converged.	0,04	3,25	0,6245		2,95	Algorithm converged.	0,31	28,27		
	65-74	70	8,5	0	0	70	8,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
	>=75	33	4	0	0	21	2,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		
Baseline viral load categories	<=10^5 copies/mL	210	25,4	0	0	209	25,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		
	>10^5 copies/mL - <=10^6 copies/mL	90	10,9	0	0	123	14,9	1	0,8	0	Algorithm converged.	NE	NE	-0,813	Algorithm converged.	-2,4	0,77	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	14,4	1	0,8	125	15,1	1	0,8	1,05	Algorithm converged.	0,06	16,99	0,04	Algorithm converged.	-2,22	2,31	1,05	Algorithm converged.	0,07	16,6	1		0,95	Algorithm converged.	0,06	15,05		
	>10^7 copies/mL	363	43,9	0	0	346	41,8	1	0,3	0	Algorithm converged.	NE	NE	-0,289	Algorithm converged.	-0,85	0,28	NE	*	Algorithm not converged.	NE	NE	0,488		NE	*	Algorithm not converged.	NE	NE
	Unknown	45	5,4	0	0	25	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		
Country	USA	785	94,9	1	0,1	787	95	2	0,3	0,5	Algorithm converged.	0,05	5,53	-0,127	Algorithm converged.	-0,56	0,3	0,5	Algorithm converged.	0,05	5,52	1	0,404	1,99	Algorithm converged.	0,18	21,96		
	MEX	42	5,1	0	0	41	5	1	2,4	0	Algorithm converged.	NE	NE	-2,439	Algorithm converged.	-7,16	2,28	NE	*	Algorithm not converged.	NE	NE	0,494		NE	*	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: 118-6-ae-raw-toxgr4

POPULATION: Safety
 ENDPOINT: AEs grade 5 (AEs leading to death)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	827	100	1	0,1	828	100	1	0,1	1	0,1	1	Algorithm converged.	0,06	16,03	0	Algorithm converged.	-0,33	0,33	1	Algorithm converged.	0,06	15,98	1		1	Algorithm converged.	0,06	15,94	
Sex	Male	405	49	1	0,2	381	46	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,24	0,73	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	*	Algorithm not converged.	NE	NE
	Female	422	51	0	0	447	54	1	0,2	0		Algorithm converged.	NE	NE	-0,224	Algorithm converged.	-0,66	0,21	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
Age	18-64	724	87,5	1	0,1	737	89	1	0,1	1,02		Algorithm converged.	0,06	16,31	0,002	Algorithm converged.	-0,38	0,38	1,02		Algorithm converged.	0,06	16,24	1		0,98		Algorithm converged.	0,06	15,68
	65-74	70	8,5	0	0	70	8,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>=75	33	4	0	0	21	2,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	210	25,4	1	0,5	209	25,2	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,45	1,41	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	90	10,9	0	0	123	14,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	14,4	0	0	125	15,1	1	0,8	0		Algorithm converged.	NE	NE	-0,8	Algorithm converged.	-2,36	0,76	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	>10^7 copies/mL	363	43,9	0	0	346	41,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	Unknown	45	5,4	0	0	25	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Country	USA	785	94,9	1	0,1	787	95	1	0,1	1		Algorithm converged.	0,06	16,06	0	Algorithm converged.	-0,35	0,35	1		Algorithm converged.	0,06	16	1	1	1		Algorithm converged.	0,06	15,92
	MEX	42	5,1	0	0	41	5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-7-ae-raw-toxgr5

POPULATION: Safety
 ENDPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Interaction Test		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	827	100	9	1,1	828	100	29	3,5	0,3	Algorithm converged.	0,14	0,64	-2,414	Algorithm converged.	-3,85	-0,98	0,31	Algorithm converged.	0,15	0,65	0,001		3,22	Algorithm converged.	1,53	6,76
Sex	Male	405	49	6	1,5	381	46	17	4,5	0,32	Algorithm converged.	0,13	0,83	-2,98	Algorithm converged.	-5,36	-0,6	0,33	Algorithm converged.	0,13	0,83	0,0133	0,7745	3,01	Algorithm converged.	1,2	7,56
	Female	422	51	3	0,7	447	54	12	2,7	0,26	Algorithm converged.	0,07	0,93	-1,974	Algorithm converged.	-3,67	-0,27	0,26	Algorithm converged.	0,08	0,93	0,0347		3,78	Algorithm converged.	1,07	13,29
Age	18-64	724	87,5	6	0,8	737	89	18	2,4	0,33	Algorithm converged.	0,13	0,85	-1,614	Algorithm converged.	-2,91	-0,32	0,34	Algorithm converged.	0,14	0,85	0,0153	0,5757	2,95	Algorithm converged.	1,18	7,38
	65-74	70	8,5	1	1,4	70	8,5	8	11,4	0,11	Algorithm converged.	0,01	0,92	-10	Algorithm converged.	-17,95	-2,05	0,13	Algorithm converged.	0,02	0,97	0,0332		8	Algorithm converged.	1,03	62,29
	>=75	33	4	2	6,1	21	2,5	3	14,3	0,39	Algorithm converged.	0,06	2,54	-8,225	Algorithm converged.	-25,26	8,81	0,42	Algorithm converged.	0,08	2,33	0,366		2,36	Algorithm converged.	0,43	12,95
Baseline viral load categories	<=10^5 copies/mL	210	25,4	2	1	209	25,2	2	1	1	Algorithm converged.	0,14	7,13	-0,005	Algorithm converged.	-1,87	1,86	1	Algorithm converged.	0,14	7	1	0,3782	1	Algorithm converged.	0,14	7,07
	>10^5 copies/mL - <=10^6 copies/mL	90	10,9	0	0	123	14,9	4	3,3	0	Algorithm converged.	NE	NE	-3,252	Algorithm converged.	-6,39	-0,12	NE	Algorithm not converged.	NE	NE	0,1395		NE	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	14,4	1	0,8	125	15,1	5	4	0,2	Algorithm converged.	0,02	1,77	-3,16	Algorithm converged.	-6,97	0,65	0,21	Algorithm converged.	0,02	1,77	0,2138		4,76	Algorithm converged.	0,56	40,15
	>10^7 copies/mL	363	43,9	6	1,7	346	41,8	18	5,2	0,31	Algorithm converged.	0,12	0,78	-3,549	Algorithm converged.	-6,23	-0,87	0,32	Algorithm converged.	0,13	0,79	0,009		3,15	Algorithm converged.	1,26	7,84
	Unknown	45	5,4	0	0	25	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Country	USA	785	94,9	9	1,1	787	95	26	3,3	0,34	Algorithm converged.	0,16	0,73	-2,157	Algorithm converged.	-3,61	-0,7	0,35	Algorithm converged.	0,16	0,74	0,0038	0,1839	2,88	Algorithm converged.	1,36	6,11
	MEX	42	5,1	0	0	41	5	3	7,3	0	Algorithm converged.	NE	NE	-7,317	Algorithm converged.	-15,29	0,65	NE	Algorithm not converged.	NE	NE	0,116		NE	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-8-ae-raw-any.sae

POPULATION: Safety
 ENDPOINT: Any SAEs (excluding disease related events)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	827	100	7	0,8	828	100	21	2,5	0,33	Algorithm converged.	0,14	0,78	-1,69	Algorithm converged.	-2,93	-0,45	0,33	Algorithm converged.	0,14	0,78	0,0077	Interaction Test p-value (likelihood ratio)	3	Algorithm converged.	1,28	7,01	
Sex	Male	405	49	5	1,2	381	46	13	3,4	0,35	Algorithm converged.	0,12	1	-2,178	Algorithm converged.	-4,29	-0,06	0,36	Algorithm converged.	0,13	1,01	0,0549	0,738	2,76	Algorithm converged.	0,99	7,68	
	Female	422	51	2	0,5	447	54	8	1,8	0,26	Algorithm converged.	0,06	1,24	-1,316	Algorithm converged.	-2,71	0,08	0,26	Algorithm converged.	0,06	1,24	0,1088	3,78	Algorithm converged.	0,81	17,68		
Age	18-64	724	87,5	6	0,8	737	89	13	1,8	0,47	Algorithm converged.	0,18	1,23	-0,935	Algorithm converged.	-2,09	0,22	0,47	Algorithm converged.	0,18	1,23	0,1148	0,1702	2,13	Algorithm converged.	0,81	5,57	
	65-74	70	8,5	0	0	70	8,5	5	7,1	0	NE	NE	-7,143	Algorithm not converged.	-13,18	-1,11	NE	*	Algorithm not converged.	NE	NE	0,0581	NE	*	Algorithm not converged.	NE	NE	
	>=75	33	4	1	3	21	2,5	3	14,3	0,19	Algorithm converged.	0,02	1,94	-11,255	Algorithm converged.	-27,32	4,81	0,21	Algorithm converged.	0,02	1,91	0,2871	4,71	Algorithm converged.	0,52	42,38		
Baseline viral load categories	<=10^5 copies/mL	210	25,4	2	1	209	25,2	1	0,5	2	Algorithm converged.	0,18	22,23	0,474	Algorithm converged.	-1,14	2,09	1,99	Algorithm converged.	0,18	21,78	1	0,289	0,5	Algorithm converged.	0,05	5,5	
	>10^5 copies/mL - <=10^6 copies/mL	90	10,9	0	0	123	14,9	3	2,4	0	Algorithm converged.	NE	NE	-2,439	Algorithm converged.	-5,17	0,29	NE	*	Algorithm not converged.	NE	NE	0,2645	NE	*	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	119	14,4	1	0,8	125	15,1	3	2,4	0,34	Algorithm converged.	0,04	3,36	-1,56	Algorithm converged.	-4,7	1,58	0,35	Algorithm converged.	0,04	3,32	0,6224	2,86	Algorithm converged.	0,3	27,08		
	>10^7 copies/mL	363	43,9	4	1,1	346	41,8	14	4	0,26	Algorithm converged.	0,09	0,81	-2,944	Algorithm converged.	-5,28	-0,61	0,27	Algorithm converged.	0,09	0,82	0,0157	3,67	Algorithm converged.	1,22	11,05		
	Unknown	45	5,4	0	0	25	3	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		
Country	USA	785	94,9	7	0,9	787	95	21	2,7	0,33	Algorithm converged.	0,14	0,78	-1,777	Algorithm converged.	-3,08	-0,47	0,33	Algorithm converged.	0,14	0,78	0,0078	1	2,99	Algorithm converged.	1,28	7	
	MEX	42	5,1	0	0	41	5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-9-ae-raw-anssaer

POPULATION: Safety
 ENDPOINT: AEs leading to treatment discontinuation
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio	Absolute Risk Difference				Relative Risk					Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	827	100	0	0	828	100	0	0																			
Sex	Male	405	49	0	0	381	46	0	0																			
	Female	422	51	0	0	447	54	0	0																			
Age	18-64	724	87,5	0	0	737	89	0	0																			
	65-74	70	8,5	0	0	70	8,5	0	0																			
	>=75	33	4	0	0	21	2,5	0	0																			
Baseline viral load categories	<=10 ⁵ copies/mL	210	25,4	0	0	209	25,2	0	0																			
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0	123	14,9	0	0																			
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0	125	15,1	0	0																			
	>10 ⁷ copies/mL	363	43,9	0	0	346	41,8	0	0																			
	Unknown	45	5,4	0	0	25	3	0	0																			
Country	USA	785	94,9	0	0	787	95	0	0																			
	MEX	42	5,1	0	0	41	5	0	0																			

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-10-ae-raw-aeldts

Datenschnitt 18.02.2021 (DCO1)

Verträglichkeit

AESI

POPULATION: Safety
 ENDPOINT: IRRs through day 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	827	100	2	0,2	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,09	0,58	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	*	Algorithm not converged.	NE	NE
Sex	Male	405	49	1	0,2	381	46	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,24	0,73	NE	*	Algorithm not converged.	NE	NE	1	1	NE	*	Algorithm not converged.	NE	NE
	Female	422	51	1	0,2	447	54	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,23	0,7	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	*	Algorithm not converged.	NE	NE
Age	18-64	724	87,5	1	0,1	737	89	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,13	0,41	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	*	Algorithm not converged.	NE	NE
	65-74	70	8,5	1	1,4	70	8,5	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,35	4,21	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	>=75	33	4	0	0	21	2,5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10 ⁵ copies/mL	210	25,4	0	0	209	25,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0	123	14,9	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0	125	15,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁷ copies/mL	363	43,9	1	0,3	346	41,8	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,26	0,81	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Unknown	45	5,4	1	2,2	25	3	0	0	NE	*	Algorithm not converged.	NE	NE	2,222	Algorithm converged.	-2,08	6,53	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
Country	USA	785	94,9	2	0,3	787	95	0	0	NE	*	Algorithm not converged.	NE	NE	0,255	Algorithm converged.	-0,1	0,61	NE	*	Algorithm not converged.	NE	NE	0,2492		NE	*	Algorithm not converged.	NE	NE
	MEX	42	5,1	0	0	41	5	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-11-ae-raw-rr

POPULATION: Safety
 ENDPOINT: Grade >= 3 IRRs through day 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Odds Ratio	Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event			Odds Ratio		Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	827	100	0	0	828	100	0	0																			
Sex	Male	405	49	0	0	381	46	0	0																			
	Female	422	51	0	0	447	54	0	0																			
Age	18-64	724	87,5	0	0	737	89	0	0																			
	65-74	70	8,5	0	0	70	8,5	0	0																			
	>=75	33	4	0	0	21	2,5	0	0																			
Baseline viral load categories	<=10 ⁵ copies/mL	210	25,4	0	0	209	25,2	0	0																			
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0	123	14,9	0	0																			
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0	125	15,1	0	0																			
	>10 ⁷ copies/mL	363	43,9	0	0	346	41,8	0	0																			
	Unknown	45	5,4	0	0	25	3	0	0																			
Country	USA	785	94,9	0	0	787	95	0	0																			
	MEX	42	5,1	0	0	41	5	0	0																			

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-12-ae-raw-irge3

POPULATION: Safety
 ENDPOINT: Serious IRRs through day 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	827	100	0	0	828	100	0	0																		
Sex	Male	405	49	0	0	381	46	0	0																		
	Female	422	51	0	0	447	54	0	0																		
Age	18-64	724	87,5	0	0	737	89	0	0																		
	65-74	70	8,5	0	0	70	8,5	0	0																		
	>=75	33	4	0	0	21	2,5	0	0																		
Baseline viral load categories	<=10 ⁵ copies/mL	210	25,4	0	0	209	25,2	0	0																		
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0	123	14,9	0	0																		
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0	125	15,1	0	0																		
	>10 ⁷ copies/mL	363	43,9	0	0	346	41,8	0	0																		
	Unknown	45	5,4	0	0	25	3	0	0																		
Country	USA	785	94,9	0	0	787	95	0	0																		
	MEX	42	5,1	0	0	41	5	0	0																		

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-13-ae-raw-sirr

POPULATION: Safety
 ENDPOINT: Hypersensitivity through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Odds Ratio	Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
		Patients		Event		Patients		Event			Odds Ratio		Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk		Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	n/a	827	100	0	0	828	100	0	0																						
Sex	Male	405	49	0	0	381	46	0	0																						
	Female	422	51	0	0	447	54	0	0																						
Age	18-64	724	87,5	0	0	737	89	0	0																						
	65-74	70	8,5	0	0	70	8,5	0	0																						
	>=75	33	4	0	0	21	2,5	0	0																						
Baseline viral load categories	<=10 ⁵ copies/mL	210	25,4	0	0	209	25,2	0	0																						
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0	123	14,9	0	0																						
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0	125	15,1	0	0																						
	>10 ⁷ copies/mL	363	43,9	0	0	346	41,8	0	0																						
	Unknown	45	5,4	0	0	25	3	0	0																						
Country	USA	785	94,9	0	0	787	95	0	0																						
	MEX	42	5,1	0	0	41	5	0	0																						

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-14-ae-raw-hyp

POPULATION: Safety
 ENDPOINT: Grade >= 3 Hypersensitivity through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Odds Ratio	Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event			Odds Ratio		Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk		Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	827	100	0	0	828	100	0	0																				
Sex	Male	405	49	0	0	381	46	0	0																				
	Female	422	51	0	0	447	54	0	0																				
Age	18-64	724	87,5	0	0	737	89	0	0																				
	65-74	70	8,5	0	0	70	8,5	0	0																				
	>=75	33	4	0	0	21	2,5	0	0																				
Baseline viral load categories	<=10^5 copies/mL	210	25,4	0	0	209	25,2	0	0																				
	>10^5 copies/mL - <=10^6 copies/mL	90	10,9	0	0	123	14,9	0	0																				
	>10^6 copies/mL - <=10^7 copies/mL	119	14,4	0	0	125	15,1	0	0																				
	>10^7 copies/mL	363	43,9	0	0	346	41,8	0	0																				
	Unknown	45	5,4	0	0	25	3	0	0																				
Country	USA	785	94,9	0	0	787	95	0	0																				
	MEX	42	5,1	0	0	41	5	0	0																				

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-15-ae-raw-hypge3

POPULATION: Safety
 ENDPOINT: Serious Hypersensitivity through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio	Absolute Risk Difference				Relative Risk					Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	827	100	0	0	828	100	0	0																		
Sex	Male	405	49	0	0	381	46	0	0																		
	Female	422	51	0	0	447	54	0	0																		
Age	18-64	724	87,5	0	0	737	89	0	0																		
	65-74	70	8,5	0	0	70	8,5	0	0																		
	>=75	33	4	0	0	21	2,5	0	0																		
Baseline viral load categories	<=10 ⁵ copies/mL	210	25,4	0	0	209	25,2	0	0																		
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0	123	14,9	0	0																		
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0	125	15,1	0	0																		
	>10 ⁷ copies/mL	363	43,9	0	0	346	41,8	0	0																		
	Unknown	45	5,4	0	0	25	3	0	0																		
Country	USA	785	94,9	0	0	787	95	0	0																		
	MEX	42	5,1	0	0	41	5	0	0																		

Test for action based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Feb2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-16-ae-raw-shyp

Datenschnitt 18.02.2021 (DCO1)

Verträglichkeit

SOC-PT

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference		Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Blood and lymphatic system disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Thrombocytopenia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm not converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Thrombocytosis	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	--	827	100	2	0,242	828	100	1	0,121	2,005	Algorithm converged.	0,181	22,153	0,121	Algorithm converged.	-0,289	NE	2,002	Algorithm converged.	0,182	22,04	0,6245		0,499	Algorithm converged.	0,045	5,497	
		Acute myocardial infarction	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Palpitations	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	827	100	9	1,088	828	100	6	0,725	1,507	Algorithm converged.	0,534	4,254	0,364	Algorithm converged.	-0,549	NE	1,502	Algorithm converged.	0,537	4,2	0,4352		0,666	Algorithm converged.	0,238	1,862	
		Abdominal pain upper	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Chronic gastritis	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Diarrhoea	--	827	100	1	0,121	828	100	2	0,242	0,5	Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987	
		Gastroesophageal reflux disease	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Nausea	--	827	100	6	0,726	828	100	1	0,121	6,044	Algorithm converged.	0,726	50,312	0,605	Algorithm converged.	-0,02	NE	6,007	Algorithm converged.	0,725	49,788	0,0697		0,166	Algorithm converged.	0,02	1,38	
		Peptic ulcer perforation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Vomiting	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	--	827	100	4	0,484	828	100	3	0,362	1,337	Algorithm converged.	0,298	5,99	0,121	Algorithm converged.	-0,504	NE	1,335	Algorithm converged.	0,3	5,946	0,7259		0,749	Algorithm converged.	0,168	3,337	
		Chest discomfort	--	827	100	2	0,242	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,093	NE	NE	*	Algorithm not converged.	NE	NE	0,2495	NE	Algorithm not converged.	NE	NE
		Fatigue	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Non-cardiac chest pain	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Pyrexia	--	827	100	0	0	828	100	3	0,362	NE	*	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Hepatobiliary disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
												Algorithm not converged.	NE	NE	-0,121	Algorithm not converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
												Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
Infections and infestations	--	--	827	100	12	1,451	828	100	38	4,589	0,306	Algorithm converged.	0,159	0,59	-3,138	Algorithm converged.	-4,78	NE	0,316	Algorithm converged.	0,166	0,601	0,0002		3,163	Algorithm converged.	1,665	6,009	
												Algorithm not converged.	NE	NE	0,121	Algorithm not converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
												Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
												Algorithm converged.	0,051	0,595	-1,69	Algorithm converged.	-2,74	NE	0,177	Algorithm converged.	0,052	0,601	0,0024		5,66	Algorithm converged.	1,665	19,24	
												Algorithm converged.	0,187	2,368	-0,241	Algorithm converged.	-0,988	NE	0,667	Algorithm converged.	0,189	2,357	0,7532		1,498	Algorithm converged.	0,424	5,29	
												Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
												Algorithm converged.	0,124	1,273	-0,724	Algorithm converged.	-1,606	NE	0,4	Algorithm converged.	0,126	1,272	0,1777		2,497	Algorithm converged.	0,786	7,93	
												Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
												Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
												Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Injury, poisoning and procedural complications	--	--	827	100	2	0,242	828	100	0	0	NE	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,093	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
												Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
												Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
												Algorithm converged.	0,474	2,114	0,002	Algorithm converged.	-1,241	NE	1,001	Algorithm converged.	0,48	2,087	0,9974		0,999	Algorithm converged.	0,479	2,082	
												Algorithm converged.	0,214	2,99	-0,12	Algorithm converged.	-0,829	NE	0,801	Algorithm converged.	0,216	2,972	1		1,248	Algorithm converged.	0,336	4,633	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Alanine aminotransferase increased	--	827	100	4	0,484	828	100	4	0,483	1,001	Algorithm converged.	0,25	4,017	0,001	Algorithm converged.	-0,668	NE	1,001	Algorithm converged.	0,251	3,99	1		0,999	Algorithm converged.	0,251	3,98		
		Aspartate aminotransferase increased	--	827	100	2	0,242	828	100	2	0,242	1,001	Algorithm converged.	0,141	7,125	0	Algorithm converged.	-0,473	NE	1,001	Algorithm converged.	0,141	7,091	1		0,999	Algorithm converged.	0,141	7,074		
		Blood creatine phosphokinase increased	--	827	100	2	0,242	828	100	1	0,121	2,005	Algorithm converged.	0,181	22,153	0,121	Algorithm converged.	-0,289	NE	2,002	Algorithm converged.	0,182	22,04	0,6245		0,499	Algorithm converged.	0,045	5,497		
		C-reactive protein increased	--	827	100	3	0,363	828	100	5	0,604	0,599	Algorithm converged.	0,143	2,516	-0,241	Algorithm converged.	-0,909	NE	0,601	Algorithm converged.	0,144	2,506	0,7259		1,665	Algorithm converged.	0,399	6,943		
		Fibrin D dimer increased	--	827	100	2	0,242	828	100	5	0,604	0,399	Algorithm converged.	0,077	2,063	-0,362	Algorithm converged.	-0,987	NE	0,4	Algorithm converged.	0,078	2,058	0,4521		2,497	Algorithm converged.	0,486	12,834		
		Heart rate decreased	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941		
		International normalised ratio increased	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941		
		Prothrombin time prolonged	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941		
		Serum ferritin increased	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Transaminases increased	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	827	100	3	0,363	828	100	7	0,845	0,427	Algorithm converged.	0,11	1,657	-0,483	Algorithm converged.	-1,229	NE	0,429	Algorithm converged.	0,111	1,654	0,3423		2,331	Algorithm converged.	0,605	8,981		
		Dehydration	--	827	100	0	0	828	100	3	0,362	NE	*	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	827	100	1	0,121	828	100	2	0,242	0,5	Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987		
		Hyponatraemia	--	827	100	0	0	828	100	3	0,362	NE	*	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941		
	Musculoskeletal and connective tissue disorders	--	--	827	100	3	0,363	828	100	3	0,362	1,001	Algorithm converged.	0,201	4,975	0	Algorithm converged.	-0,579	NE	1,001	Algorithm converged.	0,203	4,946	1		0,999	Algorithm converged.	0,202	4,934		
		Arthralgia	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Back pain	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Limb discomfort	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Myalgia	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pain in extremity	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	827	100	4	0,484	828	100	6	0,725	0,666		Algorithm converged.	0,187	2,368	-0,241	Algorithm converged.	-0,988	NE	0,667		Algorithm converged.	0,189	2,357	0,7532		1,498	Algorithm converged.	0,424	5,29
		Ageusia	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941
		Dizziness	--	827	100	4	0,484	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,484	Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0621		NE	Algorithm not converged.	NE	NE
		Headache	--	827	100	2	0,242	828	100	3	0,362	0,667		Algorithm converged.	0,111	4	-0,12	Algorithm converged.	-0,649	NE	0,667		Algorithm converged.	0,112	3,984	1		1,498	Algorithm converged.	0,251	8,943
		Presyncope	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Syncope	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pregnancy	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	827	100	2	0,242	828	100	1	0,121	2,005		Algorithm converged.	0,181	22,153	0,121	Algorithm converged.	-0,289	NE	2,002		Algorithm converged.	0,182	22,04	0,6245		0,499	Algorithm converged.	0,045	5,497
		Anxiety	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Depression	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Insomnia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	13	1,572	828	100	15	1,812	0,866	Algorithm converged.	0,409	1,831	-0,24	Algorithm converged.	-1,482	NE	0,868	Algorithm converged.	0,415	1,812	0,7055		1,152	Algorithm converged.	0,552	2,407	
	Acute respiratory failure	--	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Bronchospasm	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cough	--	--	827	100	4	0,484	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,484	Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0621		NE	Algorithm not converged.	NE	NE
	Dyspnoea	--	--	827	100	5	0,605	828	100	7	0,845	0,713	Algorithm converged.	0,226	2,257	-0,241	Algorithm converged.	-1,058	NE	0,715	Algorithm converged.	0,228	2,244	0,7736		1,398	Algorithm converged.	0,446	4,388	
	Dyspnoea exertional	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Epistaxis	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hypoxia	--	--	827	100	2	0,242	828	100	4	0,483	0,499	Algorithm converged.	0,091	2,734	-0,241	Algorithm converged.	-0,82	NE	0,501	Algorithm converged.	0,092	2,726	0,6869		1,998	Algorithm converged.	0,367	10,876	
	Nasal congestion	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Oropharyngeal pain	--	--	827	100	2	0,242	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,093	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
	Productive cough	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Respiratory distress	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Rhinorrhoea	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Skin and subcutaneous tissue disorders	--	--	827	100	2	0,242	828	100	3	0,362	0,667	Algorithm converged.	0,111	4	-0,12	Algorithm converged.	-0,649	NE	0,667	Algorithm converged.	0,112	3,984	1		1,498	Algorithm converged.	0,251	8,943	
	Night sweats	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pruritus	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Rash	--	--	827	100	2	0,242	828	100	2	0,242	1,001	Algorithm converged.	0,141	7,125	0	Algorithm converged.	-0,473	NE	1,001	Algorithm converged.	0,141	7,091	1		0,999	Algorithm converged.	0,141	7,074	
	Vascular disorders	--	--	827	100	1	0,121	828	100	2	0,242	0,5	Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987	
	Deep vein thrombosis	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Flushing	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Thrombophlebitis superficial	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	

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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	Blood and lymphatic system disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Thrombocytopenia		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Thrombocytosis		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	Male	405	48,972	2	0,494	381	46,014	1	0,262	1,886		Algorithm converged.	0,17	20,883	0,231	Algorithm converged.	-0,623	NE	1,881	*	Algorithm converged.	0,171	20,665	1	1	0,531	Algorithm converged.	0,048	5,838
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Palpitations		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	405	48,972	2	0,494	381	46,014	3	0,787	0,625		Algorithm converged.	0,104	3,763	-0,294	Algorithm converged.	-1,413	NE	0,627	*	Algorithm converged.	0,105	3,733	0,6777	0,2202	1,594	Algorithm converged.	0,268	9,49
			Female	422	51,028	7	1,659	447	53,986	3	0,671	2,496		Algorithm converged.	0,641	9,718	0,988	Algorithm converged.	-0,447	NE	2,472	*	Algorithm converged.	0,643	9,495	0,2123	0,405		Algorithm converged.	0,105	1,554
	Abdominal pain upper		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Chronic gastritis		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
		Diarrhoea	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	0,288	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	*	Algorithm converged.	0,066	16,881	1	0,944	NE	Algorithm converged.	0,059	15,045	
		Gastroesophageal reflux disease	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
		Nausea	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,5823	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	5	1,185	447	53,986	1	0,224	5,348		Algorithm converged.	0,622	45,964	0,961	Algorithm converged.	-0,16	NE	5,296	*	Algorithm converged.	0,621	45,146	0,1139	0,189	NE	Algorithm converged.	0,022	1,609	
		Peptic ulcer perforation	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Vomiting	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		General disorders and administration site conditions	Male	405	48,972	2	0,494	381	46,014	1	0,262	1,886		Algorithm converged.	0,17	20,883	0,231	Algorithm converged.	-0,623	NE	1,881	*	Algorithm converged.	0,171	20,665	1	0,7132	0,531	Algorithm converged.	0,048	5,838	
			Female	422	51,028	2	0,474	447	53,986	2	0,447	1,06		Algorithm converged.	0,149	7,556	0,027	Algorithm converged.	-0,875	NE	1,059	*	Algorithm converged.	0,15	7,486	1	0,944	NE	Algorithm converged.	0,134	6,672	
		Chest discomfort	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
		Fatigue	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
		Non-cardiac chest pain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pyrexia	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	405	48,972	6	1,481	381	46,014	21	5,512	0,258		Algorithm converged.	0,103	0,646	-4,03	Algorithm converged.	-6,606	NE	0,269		Algorithm converged.	0,11	0,659	0,0019	0,6151	3,72	Algorithm converged.	1,518	9,118
			Female	422	51,028	6	1,422	447	53,986	17	3,803	0,365		Algorithm converged.	0,142	0,934	-2,381	Algorithm converged.	-4,484	NE	0,374		Algorithm converged.	0,149	0,939	0,0289		2,675	Algorithm converged.	1,065	6,72
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	9	2,362	0,102		Algorithm converged.	0,013	0,811	-2,115	Algorithm converged.	-3,715	NE	0,105		Algorithm converged.	0,013	0,821	0,0093	0,4668	9,567	Algorithm converged.	1,218	75,155
			Female	422	51,028	2	0,474	447	53,986	8	1,79	0,261		Algorithm converged.	0,055	1,238	-1,316	Algorithm converged.	-2,709	NE	0,265		Algorithm converged.	0,057	1,24	0,1088		3,776	Algorithm converged.	0,807	17,681
			Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469		Algorithm converged.	0,042	5,194	-0,278	Algorithm converged.	-1,15	NE	0,47		Algorithm converged.	0,043	5,166	0,6134	0,7126	2,126	Algorithm converged.	0,194	23,35
			Female	422	51,028	3	0,711	447	53,986	4	0,895	0,793		Algorithm converged.	0,176	3,564	-0,184	Algorithm converged.	-1,369	NE	0,794		Algorithm converged.	0,179	3,529	1		1,259	Algorithm converged.	0,283	5,591
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Pneumonia	Male	405	48,972	3	0,741	381	46,014	7	1,837	0,399		Algorithm converged.	0,102	1,553	-1,097	Algorithm converged.	-2,683	NE	0,403	Algorithm converged.	0,105	1,548	0,2115	0,9208	2,48	Algorithm converged.	0,646	9,522		
			Female	422	51,028	1	0,237	447	53,986	3	0,671	0,352		Algorithm converged.	0,036	3,393	-0,434	Algorithm converged.	-1,322	NE	0,353	Algorithm converged.	0,037	3,381	0,6248		2,832	Algorithm converged.	0,296	27,121		
		Pneumonia bacterial	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Pneumonia viral	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Sepsis	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Sinusitis	Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469		Algorithm converged.	0,042	5,194	-0,278	Algorithm converged.	-1,15	NE	0,47	Algorithm converged.	0,043	5,166	0,6134	1	2,126	Algorithm converged.	0,194	23,35		
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Tooth abscess	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
		Urinary tract infection	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Injury, poisoning and procedural complications	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
		Infusion related reaction	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab																		
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk																				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL												
		Ligament sprain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237		Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE		NE		NE		NE		NE		NE		NE
	Investigations	--	Male	405	48,972	10	2,469	381	46,014	8	2,1	1,18		Algorithm converged.	0,461	3,023	0,369		Algorithm converged.	-1,718	NE	1,176		Algorithm converged.	0,469	2,948	0,7295	0,5183	0,85		Algorithm converged.	0,339	2,132		Algorithm converged.	0,402	4,983		Algorithm converged.	0,268	9,49
			Female	422	51,028	4	0,948	447	53,986	6	1,342	0,703		Algorithm converged.	0,197	2,51	-0,394		Algorithm converged.	-1,806	NE	0,706		Algorithm converged.	0,201	2,485	0,7535	1,416		Algorithm converged.	0,402	4,983		Algorithm converged.	0,268	9,49					
		Activated partial thromboplastin time prolonged	Male	405	48,972	2	0,494	381	46,014	3	0,787	0,625		Algorithm converged.	0,104	3,763	-0,294		Algorithm converged.	-1,413	NE	0,627		Algorithm converged.	0,105	3,733	0,6777	0,6973	1,594		Algorithm converged.	0,134	6,672		Algorithm converged.	0,119	4,218				
			Female	422	51,028	2	0,474	447	53,986	2	0,447	1,06		Algorithm converged.	0,149	7,556	0,027		Algorithm converged.	-0,875	NE	1,059		Algorithm converged.	0,15	7,486	1	0,944		Algorithm converged.	0,172	20,746		Algorithm converged.	0,119	4,218					
		Alanine aminotransferase increased	Male	405	48,972	3	0,741	381	46,014	2	0,525	1,414		Algorithm converged.	0,235	8,51	0,216		Algorithm converged.	-0,89	NE	1,411		Algorithm converged.	0,237	8,399	1	0,5115	0,709		Algorithm converged.	0,119	4,218		Algorithm converged.	0,172	20,746				
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21		Algorithm converged.	-0,984	NE	0,53		Algorithm converged.	0,048	5,819	1	1,888		Algorithm converged.	0,172	20,746		Algorithm converged.	0,119	4,218					
		Aspartate aminotransferase increased	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247		Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,2042	NE		Algorithm not converged.	NE	NE		Algorithm not converged.	NE	NE				
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21		Algorithm converged.	-0,984	NE	0,53		Algorithm converged.	0,048	5,819	1	1,888		Algorithm converged.	0,172	20,746		Algorithm converged.	0,119	4,218					
		Blood creatine phosphokinase increased	Male	405	48,972	2	0,494	381	46,014	1	0,262	1,886		Algorithm converged.	0,17	20,883	0,231		Algorithm converged.	-0,623	NE	1,881		Algorithm converged.	0,171	20,665	1	1	0,531		Algorithm converged.	0,048	5,838		Algorithm converged.	0,119	4,218				
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		Algorithm not converged.	NE	NE				
		C-reactive protein increased	Male	405	48,972	2	0,494	381	46,014	4	1,05	0,468		Algorithm converged.	0,085	2,569	-0,556		Algorithm converged.	-1,786	NE	0,47		Algorithm converged.	0,087	2,553	0,4383	0,6247	2,126		Algorithm converged.	0,059	15,045		Algorithm converged.	0,392	11,54				
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013		Algorithm converged.	-0,625	NE	1,059		Algorithm converged.	0,066	16,881	1	0,944		Algorithm converged.	0,059	15,045		Algorithm converged.	0,392	11,54					
		Fibrin D dimer increased	Male	405	48,972	2	0,494	381	46,014	2	0,525	0,94		Algorithm converged.	0,132	6,71	-0,031		Algorithm converged.	-1,027	NE	0,941		Algorithm converged.	0,133	6,645	1	0,1043	1,063		Algorithm converged.	0,15	7,509		Algorithm not converged.	NE	NE				
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671		Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498		NE		Algorithm not converged.	NE	NE		Algorithm not converged.	NE	NE				
		Heart rate decreased	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247		Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE		Algorithm not converged.	NE	NE				
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE		Algorithm not converged.	NE	NE				

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Hepatic enzyme increased	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	1	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	1	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Prothrombin time prolonged	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	1	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Serum ferritin increased	Male	405	48,972	0	0	381	46,014	2	0,525	NE *	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	Algorithm not converged.	NE	NE	0,2346		NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Transaminases increased	Male	405	48,972	1	0,247	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	Male	405	48,972	3	0,741	381	46,014	3	0,787	0,94	Algorithm converged.	0,189	4,687	-0,047	Algorithm converged.	-1,265	NE	0,941	Algorithm converged.	0,191	4,632	1	0,0566	1,063	Algorithm converged.	0,216	5,234
			Female	422	51,028	0	0	447	53,986	4	0,895	NE *	Algorithm not converged.	NE	NE	-0,895	Algorithm converged.	-1,768	NE	NE	Algorithm not converged.	NE	NE	0,1248		NE	Algorithm not converged.	NE	NE
		Dehydration	Male	405	48,972	0	0	381	46,014	1	0,262	NE *	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	2	0,447	NE *	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	Male	405	48,972	1	0,247	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	0,3246	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	0	0	447	53,986	1	0,224	NE *	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	Male	405	48,972	0	0	381	46,014	2	0,525	NE *	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	Algorithm not converged.	NE	NE	0,2346	1	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	Male	405	48,972	2	0,494	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,494	Algorithm converged.	-0,189	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	0,0579	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	3	0,671	0,352		Algorithm converged.	0,036	3,393	-0,434	Algorithm converged.	-1,322	NE	0,353		Algorithm converged.	0,037	3,381	0,6248	2,832		Algorithm converged.	0,296	27,121
		Arthralgia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Back pain	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Limb discomfort	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Myalgia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pain in extremity	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference					Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Nervous system disorders	--	Male	405	48,972	1	0,247	381	46,014	3	0,787	0,312	Algorithm converged.	0,032	3,011	-0,54	Algorithm converged.	-1,551	NE	0,314	Algorithm converged.	0,033	3,002	0,3594	0,3715	3,189	Algorithm converged.	0,333	30,525			
			Female	422	51,028	3	0,711	447	53,986	3	0,671	1,06	Algorithm converged.	0,213	5,279	0,04	Algorithm converged.	-1,063	NE	1,059	Algorithm converged.	0,215	5,219	1		0,944	Algorithm converged.	0,192	4,652			
	Ageusia		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045			
	Dizziness		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	3	0,711	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,711	Algorithm converged.	-0,091	NE	NE	*	Algorithm not converged.	NE	NE	0,1141		NE	Algorithm not converged.	NE	NE	
	Headache		Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	0,7575	1,063	Algorithm converged.	0,067	16,935			
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529	Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53	Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746			
	Presyncope		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Syncope		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Pregnancy, puerperium and perinatal conditions	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Pregnancy		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Psychiatric disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	2	0,474	447	53,986	1	0,224	2,124	Algorithm converged.	0,192	23,509	0,25	Algorithm converged.	-0,538	NE	2,118	Algorithm converged.	0,193	23,277	0,6141		0,472	Algorithm converged.	0,043	5,187			
	Anxiety		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is unreliable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
		Depression	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Insomnia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
	Reproductive system and breast disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Suppressed lactation	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Respiratory, thoracic and mediastinal disorders	--	Male	405	48,972	4	0,988	381	46,014	9	2,362	0,412		Algorithm converged.	0,126	1,35	-1,375	Algorithm converged.	-3,178	NE	0,418		Algorithm converged.	0,13	1,346	0,1653	0,0837	2,392	Algorithm converged.	0,743	7,702	
			Female	422	51,028	9	2,133	447	53,986	6	1,342	1,602		Algorithm converged.	0,565	4,539	0,79	Algorithm converged.	-0,953	NE	1,589		Algorithm converged.	0,57	4,426	0,3715	0,629		Algorithm converged.	0,226	1,753	
		Acute respiratory failure	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Bronchospasm	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Cough	Male	405	48,972	2	0,494	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,494	Algorithm converged.	-0,189	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	2	0,474	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,474	Algorithm converged.	-0,181	NE	NE	*	Algorithm not converged.	NE	NE	0,2355		NE	Algorithm not converged.	NE	NE	
		Dyspnoea	Male	405	48,972	2	0,494	381	46,014	5	1,312	0,373		Algorithm converged.	0,072	1,935	-0,819	Algorithm converged.	-2,15	NE	0,376		Algorithm converged.	0,073	1,928	0,2735	0,2314	2,657	Algorithm converged.	0,519	13,616	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

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If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	3	0,711	447	53,986	2	0,447	1,593	Algorithm converged.	0,265	9,581	0,263	Algorithm converged.	-0,749	NE	1,589	Algorithm converged.	0,267	9,462	0,6783		0,629	Algorithm converged.	0,106	3,748		
		Dyspnoea exertional	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Epistaxis	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Hypoxia	Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233	Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	0,235	Algorithm converged.	0,026	2,095	0,2041	0,0943	4,252	Algorithm converged.	0,477	37,872		
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	Algorithm not converged.	NE	NE	
		Nasal congestion	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Oropharyngeal pain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	2	0,474	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,474	Algorithm converged.	-0,181	NE	NE	*	Algorithm not converged.	NE	NE	0,2355	NE	Algorithm not converged.	NE	NE	
		Productive cough	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Respiratory distress	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Rhinorrhoea	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	Algorithm not converged.	NE	NE	
	Skin and subcutaneous tissue disorders	--	Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469	Algorithm converged.	0,042	5,194	-0,278	Algorithm converged.	-1,15	NE	0,47	Algorithm converged.	0,043	5,166	0,6134	0,6625	2,126	Algorithm converged.	0,194	23,35		
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1	0,944	Algorithm converged.	0,059	15,045			

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Night sweats	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Pruritus	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Rash	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941		Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941		Algorithm converged.	0,059	14,987	1	0,9526	1,063		Algorithm converged.	0,067	16,935	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059		Algorithm converged.	0,066	16,881	1		0,944		Algorithm converged.	0,059	15,045	
	Vascular disorders --		Male	405	48,972	0	0	381	46,014	2	0,525	NE	*	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	0,0459	NE		Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE		Algorithm not converged.	NE	NE	
		Deep vein thrombosis	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE		Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE		
		Flushing	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE		Algorithm not converged.	NE	NE	
		Thrombophlebitis superficial	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE		Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Age	Blood and lymphatic system disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Thrombocytopenia		18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE *	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Thrombocytosis		18-64	724	87,545	0	0	737	89,01	1	0,136	NE *	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	18-64	724	87,545	2	0,276	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,276	Algorithm converged.	-0,106	NE	NE *	Algorithm not converged.	NE	NE	0,2454		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE *	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE *	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE *	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		18-64	724	87,545	0	0	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE *	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE *	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE
	Palpitations		18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE *	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Gastrointestinal disorders	--		18-64	724	87,545	9	1,243	737	89,01	4	0,543	2,307	Algorithm converged.	0,707	7,524	0,7	Algorithm converged.	-0,265	NE	2,29	Algorithm converged.	0,709	7,404	0,1741	0,0894	0,437	Algorithm converged.	0,135	1,411		
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE *	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE *	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
Abdominal pain upper			18-64	724	87,545	0	0	737	89,01	1	0,136	NE *	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Chronic gastritis			18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Diarrhoea			18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508	Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509	Algorithm converged.	0,046	5,601	1		1,965	Algorithm converged.	0,179	21,62		
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Gastroesophageal reflux disease			18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Nausea			18-64	724	87,545	6	0,829	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,829	Algorithm converged.	0,168	NE	NE	*	Algorithm not converged.	NE	NE	0,0147		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE *	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Peptic ulcer perforation			18-64	724	87,545	0	0	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE *	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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POPULATION: SAFETY

ENDPOINT: Any AEs

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Vomiting	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	724	87,545	4	0,552	737	89,01	3	0,407	1,359		Algorithm converged.	0,303	6,095	0,145	Algorithm converged.	-0,564	NE	1,357		Algorithm converged.	0,305	6,043	0,7236		0,737	Algorithm converged.	0,165	3,28	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chest discomfort	18-64	724	87,545	2	0,276	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,276	Algorithm converged.	-0,106	NE	NE	*	Algorithm not converged.	NE	NE	0,2454		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fatigue	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	18-64	724	87,545	0	0	737	89,01	3	0,407	NE	*	Algorithm not converged.	NE	NE	-0,407	Algorithm converged.	-0,867	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value es based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Infections and infestations	18-64	724	87,545	6	0,829	737	89,01	28	3,799	0,212		Algorithm converged.	0,087	0,514	-2,97	Algorithm converged.	-4,501	NE	0,218		Algorithm converged.	0,091	0,524	0,0002	NE	4,584	Algorithm converged.	1,91	11,005	
			65-74	70	8,464	3	4,286	70	8,454	9	12,857	0,303		Algorithm converged.	0,079	1,173	-8,571	Algorithm converged.	-17,736	NE	0,333		Algorithm converged.	0,094	1,18	0,1284	3	Algorithm converged.	0,848	10,618		
			>=75	33	3,99	3	9,091	21	2,536	1	4,762	2		Algorithm converged.	0,194	20,614	4,329	Algorithm converged.	-9,056	NE	1,909		Algorithm converged.	0,212	17,162	1	0,524	Algorithm converged.	0,058	4,709		
		Bacteraemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchitis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm not converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		COVID-19	18-64	724	87,545	2	0,276	737	89,01	13	1,764	0,154		Algorithm converged.	0,035	0,686	-1,488	Algorithm converged.	-2,512	NE	0,157		Algorithm converged.	0,035	0,692	0,0071	0,9431	6,385	Algorithm converged.	1,446	28,196	
			65-74	70	8,464	1	1,429	70	8,454	4	5,714	0,239		Algorithm converged.	0,026	2,195	-4,286	Algorithm converged.	-10,393	NE	0,25		Algorithm converged.	0,029	2,181	0,3659		4	Algorithm converged.	0,458	34,897	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	18-64	724	87,545	1	0,138	737	89,01	3	0,407	0,338		Algorithm converged.	0,035	3,261	-0,269	Algorithm converged.	-0,802	NE	0,339		Algorithm converged.	0,035	3,254	0,6245	0,171	2,947	Algorithm converged.	0,307	28,266	
			65-74	70	8,464	1	1,429	70	8,454	3	4,286	0,324		Algorithm converged.	0,033	3,19	-2,857	Algorithm converged.	-8,356	NE	0,333		Algorithm converged.	0,036	3,127	0,6195		3	Algorithm converged.	0,32	28,146	

Test for interaction based on RR (Log-binomial regression).

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		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			≥75	33	3.99	2	6,061	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	6,061	Algorithm converged.	-2,08	NE	NE	*	Algorithm not converged.	NE	NE	0,5157		NE	Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	18-64	724	87,545	2	0,276	737	89,01	8	1,085	0,252		Algorithm converged.	0,053	1,193	-0,809	Algorithm converged.	-1,649	NE	0,254		Algorithm converged.	0,054	1,194	0,1083	0,6464	3,929	Algorithm converged.	0,837	18,441
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0	Algorithm converged.	-3,931	NE	1		Algorithm converged.	0,064	15,673	1		1	Algorithm converged.	0,064	15,673
			≥75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732	Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571	Algorithm converged.	0,104	23,79
		Pneumonia bacterial	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			≥75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			≥75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinusitis	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0	Algorithm converged.	-3,931	NE	1		Algorithm converged.	0,064	15,673	1		1	Algorithm converged.	0,064	15,673
			≥75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tooth abscess	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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POPULATION: SAFETY

ENDPOINT: Any AEs

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab												
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
	Injury, poisoning and procedural complications	--	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	2	2,857	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	2,857		Algorithm converged.	-1,046	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Infusion related reaction	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Ligament sprain	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
	Investigations	--	18-64	724	87,545	13	1,796	737	89,01	13	1,764	1,018		Algorithm converged.	0,469	2,212	0,032		Algorithm converged.	-1,324	NE	1,018		Algorithm converged.	0,475	2,181	0,9635	0,9999	0,982		Algorithm converged.	0,459	2,105					
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0		Algorithm converged.	-3,931	NE	1		Algorithm converged.	0,064	15,673	1		1		Algorithm converged.	0,064	15,673					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Activated partial thromboplastin time prolonged	18-64	724	87,545	4	0,552	737	89,01	5	0,678	0,813		Algorithm converged.	0,218	3,041	-0,126		Algorithm converged.	-0,928	NE	0,814		Algorithm converged.	0,22	3,021	1		1,228		Algorithm converged.	0,331	4,555					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Alanine aminotransferase increased	18-64	724	87,545	3	0,414	737	89,01	4	0,543	0,762	Algorithm converged.	0,17	3,419	-0,128	Algorithm converged.	-0,836	NE	0,763	Algorithm converged.	0,171	3,399	1		1,31	Algorithm converged.	0,294	5,832	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508	Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509	Algorithm converged.	0,046	5,601	1		1,965	Algorithm converged.	0,179	21,62	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	18-64	724	87,545	2	0,276	737	89,01	1	0,136	2,039	Algorithm converged.	0,184	22,533	0,141	Algorithm converged.	-0,325	NE	2,036	Algorithm converged.	0,185	22,403	0,6214		0,491	Algorithm converged.	0,045	5,405	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	18-64	724	87,545	3	0,414	737	89,01	5	0,678	0,609	Algorithm converged.	0,145	2,558	-0,264	Algorithm converged.	-1,019	NE	0,611	Algorithm converged.	0,147	2,546	0,7259		1,637	Algorithm converged.	0,393	6,826	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Fibrin D dimer increased	18-64	724	87,545	2	0,276	737	89,01	4	0,543	0,508	Algorithm converged.	0,093	2,78	-0,266	Algorithm converged.	-0,92	NE	0,509	Algorithm converged.	0,094	2,77	0,6869		1,965	Algorithm converged.	0,361	10,693	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE *	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Heart rate decreased	18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value es based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		International normalised ratio increased	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Prothrombin time prolonged	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Serum ferritin increased	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Transaminases increased	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE					
		Metabolism and nutrition disorders	18-64	724	87,545	3	0,414	737	89,01	2	0,271	1,529		Algorithm converged.	0,255	9,178	0,143		Algorithm converged.	-0,457	NE	1,527		Algorithm converged.	0,256	9,111	0,6843	0,052	0,655		Algorithm converged.	0,11	3,908					
			65-74	70	8,464	0	0	70	8,454	4	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714		Algorithm converged.	-11,152	NE	NE	*	Algorithm not converged.	NE	NE	0,1196		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE					
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE					
		Hyperkalaemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE					

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	3	4,286	NE	*	Algorithm not converged.	NE	NE	-4,286	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,2446		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	724	87,545	3	0,414	737	89,01	3	0,407	1,018		Algorithm converged.	0,205	5,061	0,007		Algorithm converged.	-0,649	NE	1,018		Algorithm converged.	0,206	5,027	1		0,982	Algorithm converged.	0,199	4,851
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthralgia	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Back pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Limb discomfort	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Myalgia	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pain in extremity	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	18-64	724	87,545	4	0,552	737	89,01	6	0,814	0,677		Algorithm converged.	0,19	2,409	-0,262	Algorithm converged.	-1,106	NE	0,679		Algorithm converged.	0,192	2,395	0,7532		1,474	Algorithm converged.	0,418	5,2	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Ageusia	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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If np < 5 in any treatment group, p-value es based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dizziness	18-64	724	87,545	4	0,552	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,552	Algorithm converged.	0,013	NE	NE	*	Algorithm not converged.	NE	NE	0,0601		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Headache	18-64	724	87,545	2	0,276	737	89,01	3	0,407	0,678		Algorithm converged.	0,113	4,068	-0,131	Algorithm converged.	-0,729	NE	0,679	*	Algorithm converged.	0,114	4,049	1		1,474	Algorithm converged.	0,247	8,793	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Presyncope	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Syncope	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pregnancy	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	724	87,545	2	0,276	737	89,01	1	0,136	2,039		Algorithm converged.	0,184	22,533	0,141	Algorithm converged.	-0,325	NE	2,036	*	Algorithm converged.	0,185	22,403	0,6214		0,491	Algorithm converged.	0,045	5,405	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Anxiety	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Depression	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Insomnia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Reproductive system and breast disorders	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Suppressed lactation	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	11	1,519	737	89,01	11	1,493	1,018		Algorithm converged.	0,439	2,364	0,027		Algorithm converged.	-1,222	NE	1,018		Algorithm converged.	0,444	2,333	0,9665	0,1566	0,982		Algorithm converged.	0,429	2,252	
			65-74	70	8,464	2	2,857	70	8,454	2	2,857	1		Algorithm converged.	0,137	7,305	0		Algorithm converged.	-5,519	NE	1		Algorithm converged.	0,145	6,902	1	1		Algorithm converged.	0,145	6,902		
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524	*	Algorithm not converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference		Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271	Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchospasm	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cough	18-64	724	87,545	4	0,552	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,552	Algorithm converged.	0,013	NE	NE	*	Algorithm not converged.	NE	NE	0,0601		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspnoea	18-64	724	87,545	4	0,552	737	89,01	4	0,543	1,018		Algorithm not converged.	0,254	4,086	0,01	Algorithm converged.	-0,747	NE	1,018		Algorithm converged.	0,256	4,055	1	0,1834	0,982		Algorithm not converged.	0,247	3,913	
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0	Algorithm converged.	-3,931	NE	1		Algorithm converged.	0,064	15,673	1		1		Algorithm not converged.	0,064	15,673	
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524	Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE	
		Dyspnoea exertional	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Epistaxis	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	18-64	724	87,545	2	0,276	737	89,01	3	0,407	0,678		Algorithm converged.	0,113	4,068	-0,131	Algorithm converged.	-0,729	NE	0,679		Algorithm converged.	0,114	4,049	1		1,474		Algorithm converged.	0,247	8,793	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Nasal congestion	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Oropharyngeal pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Productive cough	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory distress	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhinorrhoea	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Skin and subcutaneous tissue disorders	--	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508		Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509		Algorithm converged.	0,046	5,601	1	0,1884	1,965		Algorithm converged.	0,179	21,62
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE	
		Night sweats	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < = 5 in any treatment group, p-value es based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Pruritus	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rash	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508	*	Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509	*	Algorithm converged.	0,046	5,601	1		1,965	Algorithm converged.	0,179	21,62	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vascular disorders --	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
		Deep vein thrombosis	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Flushing	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Baseline viral load categories	Blood and lymphatic system disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombocytopenia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombocytosis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1		1,049	Algorithm converged.	0,066	16,707		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np < 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Acute myocardial infarction	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	1	0.84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0.84	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4877		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Palpitations	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	<=10^5 copies/mL	210	25.393	2	0.952	209	25,242	1	0.478	2		Algorithm converged.	0.18	22.226	0.474		Algorithm converged.	-1.139	NE	1.99		Algorithm converged.	0.182	21.784	1	0.1889	0.502		Algorithm converged.	0.046	5.498
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	1	1.111	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	1.111		Algorithm converged.	-1.054	NE	NE	*	Algorithm not converged.	NE	NE	0.4225		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	2	1.6	NE	*	Algorithm not converged.	NE	NE	-1.6		Algorithm converged.	-3.8	NE	NE	*	Algorithm not converged.	NE	NE	0.4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	4	1.102	346	41,787	3	0.867	1.274		Algorithm converged.	0.283	5.734	0.235		Algorithm converged.	-1.217	NE	1.271		Algorithm converged.	0.287	5.637	1	0.787		Algorithm converged.	0.177	3.49	
			Unknown	45	5.441	2	4.444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4.444		Algorithm converged.	-1.577	NE	NE	*	Algorithm not converged.	NE	NE	0.5342		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Abdominal pain upper	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chronic gastritis	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	1	1,111	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	1,111	Algorithm converged.	-1,054	NE	NE	*	Algorithm not converged.	NE	NE	0,4225		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Diarrhoea	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	2	0,578	0,475		Algorithm converged.	0,043	5,264	-0,303	Algorithm converged.	-1,266	NE	0,477		Algorithm converged.	0,043	5,232	0,6157	2,098	Algorithm converged.	0,191	23,036	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Nausea	<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	3	0,826	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,826	Algorithm converged.	-0,105	NE	NE	*	Algorithm not converged.	NE	NE	0,2494		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444	Algorithm converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10^5 copies/mL	210	25.393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952	Algorithm converged.	-0,361	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,1489	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911	*	Algorithm converged.	0,173	21,175	0,262	Algorithm converged.	-0,687	NE	1,906	*	Algorithm converged.	0,174	20,929	1		0,525	Algorithm converged.	0,048	5,759
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo									Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Chest discomfort	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^7 copies/mL	363	43.894	2	0.551	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.551	*	Algorithm not converged.	-0.211	NE	NE	*	Algorithm not converged.	NE	NE	0.4996	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Fatigue	<=10^5 copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476	*	Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Non-cardiac chest pain	<=10^5 copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476	*	Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Pyrexia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	*	Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8	*	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

Program: t-ae-raw-soc.sas
Output: 119-1f-ae-raw-soc-anyae-fs

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
	Hepatobiliary disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41,787	1	0.289	0.953		Algorithm converged.	0.059	15,297	-0.014		Algorithm converged.	-0.795	NE	0.953		Algorithm converged.	0.06	15,179	1		1.049		Algorithm converged.	0.066	16,707
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Cholecystitis acute																														
			<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Hyperbilirubinaemia																														
			<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Infections and infestations																														
			<=10^5 copies/mL	210	25.393	2	0.952	209	25,242	6	2,871	0.325		Algorithm converged.	0.065	1,631	-1,918		Algorithm converged.	-4.536	NE	0.332		Algorithm converged.	0.068	1,625	0.175	0.9979	3.014		Algorithm converged.	0.615	14,764
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	1	1.111	123	14,855	5	4,065	0.265		Algorithm converged.	0.03	2,31	-2,954		Algorithm converged.	-7.061	NE	0.273		Algorithm converged.	0.032	2,299	0.4047		3.659		Algorithm converged.	0.435	30,778
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	2	1.681	125	15,097	7	5,6	0.288		Algorithm converged.	0.059	1,416	-3,919		Algorithm converged.	-8.565	NE	0.3		Algorithm converged.	0.064	1,416	0.1727		3.332		Algorithm converged.	0.706	15,719
			>10^7 copies/mL	363	43.894	7	1.928	346	41,787	20	5,78	0.321		Algorithm converged.	0.134	0,768	-3,852		Algorithm converged.	-6.689	NE	0.334		Algorithm converged.	0.143	0,779	0.0074		2.998		Algorithm converged.	1.284	6,999
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Bacteraemia <=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	* Algorithm not converged.	NE	NE	0.275	*	Algorithm not converged.	-0.264	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Bronchitis <=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	1	0.478	NE	* Algorithm not converged.	NE	NE	-0.478	*	Algorithm converged.	-1.414	NE	NE	*	Algorithm not converged.	NE	NE	0.4988		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	* Algorithm not converged.	NE	NE	0.275	*	Algorithm converged.	-0.264	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			COVID-19 <=10 ⁵ copies/mL	210	25.393	1	0.476	209	25.242	3	1.435	0.329	Algorithm converged.	0.034	3.184	-0.959		Algorithm converged.	-2.821	NE	0.332	*	Algorithm converged.	0.035	3.163	0.372	0.4781	3.014	Algorithm converged.	0.316	28.744	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	1	1.111	123	14.855	2	1.626	0.68	Algorithm converged.	0.061	7.614	-0.515		Algorithm converged.	-3.627	NE	0.683	*	Algorithm converged.	0.063	7.42	1		1.463	Algorithm converged.	0.135	15.891	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	3	2.4	NE	* Algorithm not converged.	NE	NE	-2.4	*	Algorithm converged.	-5.083	NE	NE	*	Algorithm not converged.	NE	NE	0.2474		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	9	2.601	0.103	Algorithm converged.	0.013	0.821	-2.326	*	Algorithm converged.	-4.087	NE	0.106	*	Algorithm converged.	0.013	0.832	0.0096		9.442	Algorithm converged.	1.203	74.137	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			COVID-19 pneumonia <=10 ⁵ copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	* Algorithm not converged.	NE	NE	0.476		Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	0.317	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	2	1.626	NE	* Algorithm not converged.	NE	NE	-1.626	*	Algorithm converged.	-3.861	NE	NE	*	Algorithm not converged.	NE	NE	0.5097		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	1	0.84	125	15.097	1	0.8	1.051	Algorithm converged.	0.065	16.994	0.04		Algorithm converged.	-2.224	NE	1.05	*	Algorithm converged.	0.066	16.603	1		0.952	Algorithm converged.	0.06	15.048	
			>10 ⁷ copies/mL	363	43.894	2	0.551	346	41.787	3	0.867	0.633	Algorithm converged.	0.105	3.814	-0.316	*	Algorithm converged.	-1.555	NE	0.635	*	Algorithm converged.	0.107	3.78	0.6794		1.574	Algorithm converged.	0.265	9.361	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	

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 * indicates convergence problem. Result is uninterpretable.
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POPULATION: SAFETY

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pharyngitis streptococcal	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	<=10^5 copies/mL	210	25.393	0	0	209	25,242	2	0,957	NE	*	Algorithm not converged.	NE	NE	-0,957	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,2482	0,5416	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	1	0,84	125	15,097	2	1,6	0,521	*	Algorithm converged.	0,047	5,824	-0,76	*	Algorithm converged.	NE	NE	0,525	*	Algorithm converged.	0,048	5,716	1		1,904		Algorithm converged.	0,175	20,723
			>10^7 copies/mL	363	43.894	3	0,826	346	41,787	5	1,445	0,568	*	Algorithm converged.	0,135	2,396	-0,619	*	Algorithm converged.	NE	NE	0,572	*	Algorithm converged.	0,138	2,375	0,4959		1,749		Algorithm converged.	0,421	7,261
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia viral	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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Model: Unstratified analysis

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Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Sepsis	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,488	NE	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Sinusitis	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1	1,049	Algorithm converged.	0,066	16,707	Algorithm converged.	0,066	16,707
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Tooth abscess	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Urinary tract infection	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

|| np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	1	2.222	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	2.222		Algorithm converged.	-2.085	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
		Infusion related reaction	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	1	2.222	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	2.222		Algorithm converged.	-2.085	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
	Investigations	--	<=10^5 copies/mL	210	25.393	6	2.857	209	25.242	2	0.957	3.044		Algorithm converged.	0.607	15.259	1.9		Algorithm converged.	-0.711	NE	2.986		Algorithm converged.	0.61	14.624	0.2843	0.1467	0.335		Algorithm converged.	0.068	1.64	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	1	1.111	123	14.855	4	3.252	0.334		Algorithm converged.	0.037	3.042	-2.141		Algorithm converged.	-5.951	NE	0.342		Algorithm converged.	0.039	3.006	0.3993		2.927		Algorithm converged.	0.333	25.746	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	1	0.84	125	15.097	4	3.2	0.256		Algorithm converged.	0.028	2.327	-2.36		Algorithm converged.	-5.854	NE	0.263		Algorithm converged.	0.03	2.316	0.3706		3.808		Algorithm converged.	0.432	33.582	
			>10^7 copies/mL	363	43.894	6	1.653	346	41.787	4	1.156	1.437		Algorithm converged.	0.402	5.136	0.497		Algorithm converged.	-1.232	NE	1.43		Algorithm converged.	0.407	5.023	0.7529		0.699		Algorithm converged.	0.199	2.457	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Activated partial thromboplastin time prolonged	<=10^5 copies/mL	210	25.393	2	0.952	209	25.242	1	0.478	2		Algorithm converged.	0.18	22.226	0.474		Algorithm converged.	-1.139	NE	1.99		Algorithm converged.	0.182	21.784	1	0.2272	0.502		Algorithm converged.	0.046	5.498
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813		Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	2	1.6	NE	*	Algorithm not converged.	NE	NE	-1.6		Algorithm converged.	-3.8	NE	NE	*	Algorithm not converged.	NE	NE	0.4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	2	0.551	346	41.787	1	0.289	1.911		Algorithm converged.	0.173	21.175	0.262		Algorithm converged.	-0.687	NE	1.906		Algorithm converged.	0.174	20.929	1		0.525		Algorithm converged.	0.048	5.759
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	<=10^5 copies/mL	210	25.393	2	0.952	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.952		Algorithm converged.	-0.361	NE	NE	*	Algorithm not converged.	NE	NE	0.4988	0.2413	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	1	1.111	123	14.855	2	1.626	0.68		Algorithm converged.	0.061	7.614	-0.515		Algorithm converged.	-3.627	NE	0.683		Algorithm converged.	0.063	7.42	1		1.463		Algorithm converged.	0.135	15.891
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8		Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	1	0.289	0.953		Algorithm converged.	0.059	15.297	-0.014		Algorithm converged.	-0.795	NE	0.953		Algorithm converged.	0.06	15.179	1		1.049		Algorithm converged.	0.066	16.707
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	<=10^5 copies/mL	210	25.393	2	0.952	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.952		Algorithm converged.	-0.361	NE	NE	*	Algorithm not converged.	NE	NE	0.4988		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8		Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813		Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	2	0.551	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.551		Algorithm converged.	-0.211	NE	NE	*	Algorithm not converged.	NE	NE	0.4996		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE
		C-reactive protein increased	<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	1	0,478	0,995	*	Algorithm converged.	0,062	16,017	-0,002	*	Algorithm converged.	-1,322	NE	NE	0,995	*	Algorithm converged.	0,063	15,806	1	0,3034	1,005	Algorithm converged.	0,063	15,958
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	*	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911	*	Algorithm converged.	0,173	21,175	0,262	*	Algorithm converged.	-0,687	NE	1,906	*	Algorithm converged.	0,174	20,929	1		0,525	Algorithm converged.	0,048	5,759	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Fibrin D dimer increased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	2	0,957	NE	*	Algorithm not converged.	NE	NE	-0,957	*	Algorithm converged.	-2,277	NE	NE	*	Algorithm not converged.	NE	NE	0,2482	0,2329	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911	*	Algorithm converged.	0,173	21,175	0,262	*	Algorithm converged.	-0,687	NE	1,906	*	Algorithm converged.	0,174	20,929	1		0,525	Algorithm converged.	0,048	5,759	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Heart rate decreased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Hepatic enzyme increased	<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Prothrombin time prolonged	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Serum ferritin increased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Transaminases increased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,5014	NE		Algorithm not converged.	NE	NE	NE			
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	*	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982	NE		Algorithm not converged.	NE	NE	NE	NE			
			>10^7 copies/mL	363	43,894	3	0,826	346	41,787	4	1,156	0,713		Algorithm converged.	0,158	3,207	-0,33	*	Algorithm converged.	-1,791	NE	0,715	*	Algorithm converged.	0,161	3,171	0,7192	1,399		Algorithm converged.	0,315	6,205	NE	NE			
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
		Dehydration	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	*	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982	NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE		Algorithm converged.	NE	NE	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Hyperkalaemia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Hypokalaemia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014	*	Algorithm converged.	-0,795	NE	0,953	*	Algorithm converged.	0,06	15,179	1	1,049		Algorithm converged.	0,066	16,707	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Hypnatraemia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
				>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE		
				>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
				>10^7 copies/mL	363	43,894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	*	Algorithm converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Type 2 diabetes mellitus	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014	*	Algorithm converged.	-0,795	NE	0,953	*	Algorithm converged.	0,06	15,179	1	1,049	NE	NE	NE	NE	NE	0,066	16,707	NE	NE
				Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Musculoskeletal and connective tissue disorders	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,2378	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262	*	Algorithm converged.	-0,687	NE	1,906	*	Algorithm converged.	0,174	20,929	1	0,525	NE	NE	NE	NE	NE	0,048	5,759	NE	NE
				Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Arthralgia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Back pain	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	1	0.84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0.84	*	Algorithm converged.	NE	NE	0.84	*	Algorithm not converged.	NE	NE	0.4877		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Limb discomfort	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0.275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	*	Algorithm converged.	NE	NE	0.275	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	*	Algorithm converged.	NE	NE	-2.4	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Myalgia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm converged.	NE	NE	-0.855	*	Algorithm not converged.	NE	NE	0.488		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab																			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk																			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL														
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
		Pain in extremity	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE					
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE				
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE				
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
		Rhabdomyolysis	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
	Nervous system disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	3	2,4	NE	*	Algorithm not converged.	NE	NE	-2,4	*	Algorithm converged.	-5,083	NE	NE	*	Algorithm not converged.	NE	NE	0,2474		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	2	0,578	0,953	*	Algorithm converged.	0,133	6,802	-0,027	*	Algorithm converged.	-1,131	NE	0,953	*	Algorithm converged.	0,135	6,729	1		1,049		Algorithm converged.	0,149	7,407	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444	*	Algorithm converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Aeusia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953	*	Algorithm converged.	0,059	15,297	-0,014	*	Algorithm converged.	-0,795	NE	0,953	*	Algorithm converged.	0,06	15,179	1		1,049		Algorithm converged.	0,066	16,707	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Dizziness	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,551	*	Algorithm not converged.	-0,211	NE	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE		
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444	*	Algorithm not converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342		NE		Algorithm not converged.	NE	NE		
		Headache	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm not converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	*	Algorithm not converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm not converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			Unknown	45	5,441	1	2,222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2,222	*	Algorithm not converged.	-2,085	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
		Presyncope	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm not converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Syncope	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

⚠ np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab															
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
	Pregnancy, puerperium and perinatal conditions	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Pregnancy	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
	Psychiatric disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262		Algorithm converged.	-0,687	NE	1,906		Algorithm converged.	0,174	20,929	1	0,525	NE	NE	NE	0,048	5,759	NE	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Anxiety	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Insomnia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	<=10 ⁶ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	210	25.393	3	1,429	209	25,242	1	0,478	3.014		Algorithm converged.	0.311	29.218	0.95	Algorithm converged.	-0.908	NE	2,986		Algorithm converged.	0.313	28,471	0.6232	0.2777	0.335	Algorithm converged.	0.035	3,194
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	1	1,111	123	14,855	1	0,813	1,371		Algorithm converged.	0.085	22.212	0.298	Algorithm converged.	-2.387	NE	1,367		Algorithm converged.	0.087	21,56	1		0.732	Algorithm converged.	0.046	11,543
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	9	2,479	346	41,787	10	2,89	0,854		Algorithm converged.	0,343	2,128	-0,411	Algorithm converged.	-2,793	NE	0,858		Algorithm converged.	0,353	2,086	0,7351		1,166	Algorithm converged.	0,479	2,834
			Unknown	45	5,441	0	0	25	3,019	1	4	NE	*	Algorithm not converged.	NE	NE	-4	Algorithm converged.	-11,681	NE	NE	*	Algorithm not converged.	NE	NE	0,3571		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	Algorithm converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchospasm	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cough	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	4	1,102	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	1,102	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,1244	NE	NE	NE	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		Dyspnoea	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1	0,4062	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	1	1,111	123	14,855	1	0,813	1,371		Algorithm converged.	0,085	22,212	0,298		Algorithm converged.	-2,387	NE	1,367		Algorithm converged.	0,087	21,56	1	0,732	Algorithm converged.	0,046	11,543	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	3	0,826	346	41,787	4	1,156	0,713		Algorithm converged.	0,158	3,207	-0,33		Algorithm converged.	-1,791	NE	0,715		Algorithm converged.	0,161	3,171	0,7192	1,399	Algorithm converged.	0,315	6,205	
			Unknown	45	5,441	0	0	25	3,019	1	4	NE	*	Algorithm not converged.	NE	NE	-4		Algorithm converged.	-11,681	NE	NE	*	Algorithm not converged.	NE	NE	0,3571	NE	Algorithm not converged.	NE	NE	
		Dyspnoea exertional	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478		Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Epistaxis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Hypoxia	<=10 ⁵ copies/mL	210	25,393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952		Algorithm converged.	-0,361	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867	*	Algorithm converged.	NE	NE	-1,844	NE	NE	NE	0,1157		NE		Algorithm not converged.	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Nasal congestion	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	NE	NE	-0,264	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Oropharyngeal pain	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,551	*	Algorithm converged.	NE	NE	-0,211	NE	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Productive cough	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	NE	NE	-0,264	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Respiratory distress	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab															
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE						
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
		Rhinorrhoea	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
	Skin and subcutaneous tissue disorders	--	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE						
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	3	0,867	0,316		Algorithm converged.	0,033	3,051	-0,592	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	-1,707	NE	0,318	Algorithm converged.	0,033	3,04	0,3623	3,147	Algorithm converged.	0,329	30,113		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
		Night sweats	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,855	NE	NE	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
		Pruritus	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE						

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rash	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	2	0,578	0,475	*	Algorithm converged.	0,043	5,264	-0,303	*	Algorithm converged.	-1,266	NE	0,477	*	Algorithm converged.	0,043	5,232	0,6157		2,098		Algorithm converged.	0,191	23,036
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	2	0,578	0,475	*	Algorithm converged.	0,043	5,264	-0,303	*	Algorithm converged.	-1,266	NE	0,477	*	Algorithm converged.	0,043	5,232	0,6157		2,098		Algorithm converged.	0,191	23,036
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Deep vein thrombosis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Flushing	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	<=10 ⁶ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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POPULATION: SAFETY

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Blood and lymphatic system disorders	--	USA	785	94.921	1	0.127	787	95.048	1	0.127	1.003	Algorithm converged.	0.063	16.057	0	Algorithm converged.	-0.352	NE	1.003	Algorithm converged.	0.063	16	1	1	0.997	Algorithm converged.	0.063	15,919		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Thrombocytopenia		USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Thrombocytosis		USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Cardiac disorders	--	USA	785	94.921	2	0.255	787	95.048	1	0.127	2.008	Algorithm converged.	0.182	22.186	0.128	Algorithm converged.	-0.304	NE	2.005	Algorithm converged.	0.182	22.068	0.6243	1	0.499	Algorithm converged.	0.045	5,489		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Acute myocardial infarction		USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Atrial fibrillation		USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Palpitations		USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994	NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	USA	785	94.921	8	1.019	787	95.048	6	0.762	1.34	Algorithm converged.	0.463	3.881	0.257	Algorithm converged.	-0.672	NE	1.337	Algorithm converged.	0.466	3.835	0.5881	0.3042	0.748	Algorithm converged.	0.261	2,146		
			MEX	42	5.079	1	2.381	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	2.381	Algorithm converged.	-2.23	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
	Abdominal pain upper		USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic gastritis	USA	785	94,921	0	0	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	1	2,381	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	2,381		Algorithm not converged.	NE	NE	2,381		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Diarrhoea	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127		Algorithm converged.	0,045	5,532	-0,127		Algorithm converged.	0,046	5,517	1	1	1,995		Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	NE	NE	0,127		Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nausea	USA	785	94,921	6	0,764	787	95,048	1	0,127	6,054		Algorithm converged.	0,727	50,402	0,637		Algorithm converged.	0,727	50,402	0,637		Algorithm not converged.	NE	NE	0,0694	1	0,166		Algorithm converged.	0,02	1,378
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	NE	NE	-0,127		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Vomiting	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	NE	NE	-0,254		Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	785	94,921	4	0,51	787	95,048	2	0,254	2,01		Algorithm converged.	0,367	11,007	0,255		Algorithm converged.	0,367	11,007	0,255		Algorithm not converged.	NE	NE	0,4518	0,1604	0,499		Algorithm converged.	0,092	2,715
			MEX	42	5,079	0	0	41	4,952	1	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439		Algorithm not converged.	NE	NE	-2,439		Algorithm not converged.	NE	NE	0,494		NE		Algorithm not converged.	NE	NE
		Chest discomfort	USA	785	94,921	2	0,255	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,255		Algorithm converged.	NE	NE	0,255		Algorithm not converged.	NE	NE	0,2492		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fatigue	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003	*	Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	1	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439		Algorithm converged.	-7,161	NE	NE	*	Algorithm not converged.	NE	NE	0,494		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003	*	Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	12	1,529	787	95,048	35	4,447	0,334		Algorithm converged.	0,172	0,647	-2,919		Algorithm converged.	-4,595	NE	0,344	*	Algorithm converged.	0,18	0,657	0,0007	0,183	2,909	Algorithm converged.	1,522	5,563
			MEX	42	5,079	0	0	41	4,952	3	7,317	NE	*	Algorithm not converged.	NE	NE	-7,317		Algorithm converged.	-15,288	NE	NE	*	Algorithm not converged.	NE	NE	0,116		NE	Algorithm not converged.	NE	NE
		Bacteraemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Bronchitis	USA	785	94.921	1	0.127	787	95.048	1	0.127	1.003	Algorithm converged.	0.063	16.057	0	Algorithm converged.	-0.352	NE	1.003	Algorithm converged.	0.063	16	1	1	0.997	Algorithm converged.	0.063	15,919		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		COVID-19	USA	785	94.921	3	0.382	787	95.048	14	1.779	0.212	Algorithm converged.	0.061	0.74	-1.397	Algorithm converged.	-2.416	NE	0.215	Algorithm converged.	0.062	0.745	0.0123	0.2944	4.655	Algorithm converged.	1,343	16,134		
			MEX	42	5.079	0	0	41	4.952	3	7.317	NE *	Algorithm not converged.	NE	NE	-7.317	Algorithm not converged.	-15.288	NE	NE	Algorithm not converged.	NE	NE	0.116		NE	Algorithm not converged.	NE	NE		
		COVID-19 pneumonia	USA	785	94.921	4	0.51	787	95.048	6	0.762	0.667	Algorithm converged.	0.187	2.372	-0.253	Algorithm converged.	-1.039	NE	0.668	Algorithm converged.	0.189	2.359	0.7531	1	1.496	Algorithm converged.	0.424	5,281		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Pharyngitis streptococcal	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Pneumonia	USA	785	94.921	4	0.51	787	95.048	10	1.271	0.398	Algorithm converged.	0.124	1.274	-0.761	Algorithm converged.	-1.689	NE	0.401	Algorithm converged.	0.126	1.273	0.1776	1	2.494	Algorithm converged.	0.785	7,917		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Pneumonia bacterial	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Pneumonia viral	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Sepsis	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Sinusitis	USA	785	94.921	1	0.127	787	95.048	2	0.254	0.501	Algorithm converged.	0.045	5.532	-0.127	Algorithm converged.	-0.558	NE	0.501	Algorithm converged.	0.046	5.517	1	1	1.995	Algorithm converged.	0.181	21,956		

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Tooth abscess	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Urinary tract infection	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Injury, poisoning and procedural complications	USA	785	94,921	2	0,255	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,255		Algorithm converged.	-0,098	NE	NE	*	Algorithm not converged.	NE	NE	0,2492		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Infusion related reaction	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Ligament sprain	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Investigations	USA	785	94,921	14	1,783	787	95,048	14	1,779	1,003		Algorithm converged.	0,475	2,117	0,005		Algorithm converged.	-1,303	NE	1,003		Algorithm converged.	0,481	2,089	0,9946	1	0,997		Algorithm converged.	0,479	2,078					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Activated partial thromboplastin time prolonged	USA	785	94,921	4	0,51	787	95,048	5	0,635	0,801		Algorithm converged.	0,214	2,994	-0,126		Algorithm converged.	-0,872	NE	0,802		Algorithm converged.	0,216	2,976	1	1	1,247		Algorithm converged.	0,336	4,626					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Alanine aminotransferase increased	USA	785	94,921	4	0,51	787	95,048	4	0,508	1,003		Algorithm converged.	0,25	4,023	0,001		Algorithm converged.	-0,702	NE	1,003		Algorithm converged.	0,252	3,994	1	1	0,997		Algorithm converged.	0,25	3,974					

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Aspartate aminotransferase increased	USA	785	94,921	2	0,255	787	95,048	2	0,254	1,003		Algorithm converged.	0,141	7,135	0,001		Algorithm converged.	-0,497	NE	1,003		Algorithm converged.	0,142	7,099	1	1	0,997		Algorithm converged.	0,141	7,063			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Blood creatine phosphokinase increased	USA	785	94,921	2	0,255	787	95,048	1	0,127	2,008		Algorithm converged.	0,182	22,186	0,128		Algorithm converged.	-0,304	NE	2,005		Algorithm converged.	0,182	22,068	0,6243	1	0,499		Algorithm converged.	0,045	5,489			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		C-reactive protein increased	USA	785	94,921	3	0,382	787	95,048	5	0,635	0,6		Algorithm converged.	0,143	2,519	-0,253		Algorithm converged.	-0,956	NE	0,602		Algorithm converged.	0,144	2,508	0,7259	1	1,662		Algorithm converged.	0,399	6,932			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Fibrin D dimer increased	USA	785	94,921	2	0,255	787	95,048	5	0,635	0,399		Algorithm converged.	0,077	2,065	-0,381		Algorithm converged.	-1,038	NE	0,401		Algorithm converged.	0,078	2,061	0,4521	1	2,494		Algorithm converged.	0,485	12,815			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Heart rate decreased	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4994	NE		Algorithm not converged.	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Hepatic enzyme increased	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		International normalised ratio increased	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Prothrombin time prolonged	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919			

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Serum ferritin increased	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm not converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Transaminases increased	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm not converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Metabolism and nutrition disorders --	USA	785	94,921	3	0,382	787	95,048	7	0,889	0,427		Algorithm converged.	0,11	1,659	-0,507		Algorithm converged.	-1,293	NE	0,43		Algorithm converged.	0,112	1,656	0,3422	1	2,327		Algorithm converged.	0,604	8,968					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Dehydration	USA	785	94,921	0	0	787	95,048	3	0,381	NE	*	Algorithm not converged.	NE	NE	-0,381		Algorithm not converged.	-0,812	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Hyperkalaemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm not converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Hypokalaemia	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127		Algorithm converged.	-0,558	NE	0,501		Algorithm converged.	0,046	5,517	1	1	1,995		Algorithm converged.	0,181	21,956					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Hyponatraemia	USA	785	94,921	0	0	787	95,048	3	0,381	NE	*	Algorithm not converged.	NE	NE	-0,381		Algorithm not converged.	-0,812	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Type 2 diabetes mellitus	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Musculoskeletal and connective tissue disorders	--		USA	785	94.921	3	0.382	787	95.048	3	0.381	1.003	Algorithm converged.	0.202	4.982	0.001	Algorithm converged.	-0.609	NE	1.003	Algorithm converged.	0.203	4.952	1	1	0.997	Algorithm converged.	0.202	4.927	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Arthralgia			USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Back pain			USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Limb discomfort			USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Musculoskeletal pain			USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Myalgia			USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Pain in extremity			USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Rhabdomyolysis			USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Nervous system disorders	--		USA	785	94.921	4	0.51	787	95.048	6	0.762	0.667	Algorithm converged.	0.187	2.372	-0.253	Algorithm converged.	-1.039	NE	0.668	Algorithm converged.	0.189	2.359	0.7531	1	1.496	Algorithm converged.	0.424	5.281	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Ageusia	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003	*	Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Dizziness	USA	785	94,921	4	0,51	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,51		Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0619		NE		Algorithm not converged.	NE	NE					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Headache	USA	785	94,921	2	0,255	787	95,048	3	0,381	0,668		Algorithm converged.	0,111	4,006	-0,126		Algorithm converged.	-0,683	NE	0,668	*	Algorithm converged.	0,112	3,989	1	1	1,496		Algorithm converged.	0,251	8,93					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Presyncope	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Syncope	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Pregnancy, puerperium and perinatal conditions	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Pregnancy	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE					
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Psychiatric disorders	USA	785	94,921	2	0,255	787	95,048	1	0,127	2,008		Algorithm converged.	0,182	22,186	0,128		Algorithm converged.	-0,304	NE	2,005	*	Algorithm converged.	0,182	22,068	0,6243	1	0,499		Algorithm converged.	0,045	5,489					

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk																
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Anxiety	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
		Depression	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
		Insomnia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
	Reproductive system and breast disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
		Suppressed lactation	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
	Respiratory, thoracic and mediastinal disorders	--	USA	785	94,921	12	1,529	787	95,048	15	1,906	0,799		Algorithm converged.	0,372	1,718	-0,377		Algorithm converged.	-1,662	NE	0,802		Algorithm converged.	0,378	1,702	0,5649	0,2112	1,247		Algorithm converged.	0,587	2,646					
			MEX	42	5,079	1	2,381	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	2,381		Algorithm converged.	-2,23	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
		Acute respiratory failure	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE		
		Bronchospasm	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cough	USA	785	94,921	4	0,51	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,51		Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0619		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspnoea	USA	785	94,921	4	0,51	787	95,048	7	0,889	0,571		Algorithm converged.	0,166	1,957	-0,38		Algorithm converged.	-1,204	NE	0,573		Algorithm converged.	0,168	1,949	0,5474	0,1719	1,746		Algorithm converged.	0,513	5,939
			MEX	42	5,079	1	2,381	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	2,381		Algorithm converged.	-2,23	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Dyspnoea exertional	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Epistaxis	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	USA	785	94,921	2	0,255	787	95,048	4	0,508	0,5		Algorithm converged.	0,091	2,738	-0,253		Algorithm converged.	-0,863	NE	0,501		Algorithm converged.	0,092	2,729	0,6869	1	1,995		Algorithm converged.	0,366	10,86
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nasal congestion	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Oropharyngeal pain	USA	785	94,921	2	0,255	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,255		Algorithm converged.	-0,098	NE	NE	*	Algorithm not converged.	NE	NE	0,2492		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Productive cough	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Respiratory distress	USA	785	94.921	0	0	787	95.048	1	0.127	NE	*	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhinorrhoea	USA	785	94.921	1	0.127	787	95.048	0	0	NE	*	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Skin and subcutaneous tissue disorders	USA	785	94.921	2	0.255	787	95.048	3	0.381	0.668		Algorithm converged.	0.111	4.006	-0.126	Algorithm converged.	-0.683	NE	0.668		Algorithm converged.	0.112	3.989	1	1	1.496	Algorithm converged.	0.251	8.93	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Night sweats	USA	785	94.921	0	0	787	95.048	1	0.127	NE	*	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pruritus	USA	785	94.921	0	0	787	95.048	1	0.127	NE	*	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rash	USA	785	94.921	2	0.255	787	95.048	2	0.254	1.003		Algorithm converged.	0.141	7.135	0.001	Algorithm converged.	-0.497	NE	1.003		Algorithm converged.	0.142	7.099	1	1	0.997	Algorithm converged.	0.141	7.063	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vascular disorders	USA	785	94.921	1	0.127	787	95.048	2	0.254	0.501		Algorithm converged.	0.045	5.532	-0.127	Algorithm converged.	-0.558	NE	0.501		Algorithm converged.	0.046	5.517	1	1	1.995	Algorithm converged.	0.181	21.956	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Deep vein thrombosis	USA	785	94.921	0	0	787	95.048	1	0.127	NE	*	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Flushing	USA	785	94.921	1	0.127	787	95.048	0	0	NE	*	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Blood and lymphatic system disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Thrombocytopenia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm not converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Thrombocytosis	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	--	827	100	2	0,242	828	100	1	0,121	2,005	Algorithm converged.	0,181	22,153	0,121	Algorithm converged.	-0,289	NE	2,002	Algorithm converged.	0,182	22,04	0,6245		0,499	Algorithm converged.	0,045	5,497	
		Acute myocardial infarction	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Palpitations	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	827	100	9	1,088	828	100	6	0,725	1,507	Algorithm converged.	0,534	4,254	0,364	Algorithm converged.	-0,549	NE	1,502	Algorithm converged.	0,537	4,2	0,4352		0,666	Algorithm converged.	0,238	1,862	
		Abdominal pain upper	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
		Chronic gastritis	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Diarrhoea	--	827	100	1	0,121	828	100	2	0,242	0,5	Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1	1,998	Algorithm converged.	0,181	21,987		
		Gastroesophageal reflux disease	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
		Nausea	--	827	100	6	0,726	828	100	1	0,121	6,044	Algorithm converged.	0,726	50,312	0,605	Algorithm converged.	-0,02	NE	6,007	Algorithm converged.	0,725	49,788	0,0697		0,166	Algorithm converged.	0,02	1,38	
		Peptic ulcer perforation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
Vomiting	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE		
	General disorders and administration site conditions	--	--	827	100	4	0,484	828	100	3	0,362	1,337	Algorithm converged.	0,298	5,99	0,121	Algorithm converged.	-0,504	NE	1,335	Algorithm converged.	0,3	5,946	0,7259		0,749	Algorithm converged.	0,168	3,337	
		Chest discomfort	--	827	100	2	0,242	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,093	NE	NE	*	Algorithm not converged.	NE	NE	0,2495	NE	Algorithm not converged.	NE	NE
		Fatigue	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1	0,999	Algorithm converged.	0,063	15,941		
		Non-cardiac chest pain	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE
				827	100	0	0	828	100	3	0,362	NE	*	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Hepatobiliary disorders	--	--	--	827	100	1	0,121	828	100	1	0,121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941		
				827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
				827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
Infections and infestations	--	--	--	827	100	7	0,846	828	100	18	2,174	0,384	Algorithm converged.	0,16	0,925	-1,327	Algorithm converged.	-2,501	NE	0,389	Algorithm converged.	0,163	0,927	0,0269		2,568	Algorithm converged.	1,078	6,116		
				827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
				827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
				827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
				827	100	4	0,484	828	100	10	1,208	0,398		Algorithm converged.	0,124	1,273	-0,724	Algorithm converged.	-1,606	NE	0,4	Algorithm converged.	0,126	1,272	0,1777		2,497	Algorithm converged.	0,786	7,93	
				827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
				827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
				827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
				827	100	1	0,121	828	100	2	0,242	0,5		Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987	
827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE				
827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE				
Injury, poisoning and procedural complications	--	--	--	827	100	2	0,242	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,093	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
				827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
				827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
Investigations	--	--	--	827	100	14	1,693	828	100	14	1,691	1,001	Algorithm converged.	0,474	2,114	0,002	Algorithm converged.	-1,241	NE	1,001	Algorithm converged.	0,48	2,087	0,9974		0,999	Algorithm converged.	0,479	2,082		
				827	100	4	0,484	828	100	5	0,604	0,8		Algorithm converged.	0,214	2,99	-0,12	Algorithm converged.	-0,829	NE	0,801	Algorithm converged.	0,216	2,972	1		1,248	Algorithm converged.	0,336	4,633	
				827	100	4	0,484	828	100	4	0,483	1,001		Algorithm converged.	0,25	4,017	0,001	Algorithm converged.	-0,668	NE	1,001	Algorithm converged.	0,251	3,99	1		0,999	Algorithm converged.	0,251	3,98	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Aspartate aminotransferase increased	--	827	100	2	0.242	828	100	2	0.242	1,001	Algorithm converged.	0,141	7,125	0	Algorithm converged.	-0,473	NE	1,001	Algorithm converged.	0,141	7,091	1		0,999	Algorithm converged.	0,141	7,074	
		Blood creatine phosphokinase increased	--	827	100	2	0.242	828	100	1	0.121	2,005	Algorithm converged.	0,181	22,153	0,121	Algorithm converged.	-0,289	NE	2,002	Algorithm converged.	0,182	22,04	0,6245		0,499	Algorithm converged.	0,045	5,497	
		C-reactive protein increased	--	827	100	3	0.363	828	100	5	0.604	0,599	Algorithm converged.	0,143	2,516	-0,241	Algorithm converged.	-0,909	NE	0,601	Algorithm converged.	0,144	2,506	0,7259		1,665	Algorithm converged.	0,399	6,943	
		Fibrin D dimer increased	--	827	100	2	0.242	828	100	5	0.604	0,399	Algorithm converged.	0,077	2,063	-0,362	Algorithm converged.	-0,987	NE	0,4	Algorithm converged.	0,078	2,058	0,4521		2,497	Algorithm converged.	0,486	12,834	
		Heart rate decreased	--	827	100	1	0.121	828	100	0	0	NE	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	--	827	100	1	0.121	828	100	1	0.121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		International normalised ratio increased	--	827	100	1	0.121	828	100	1	0.121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Prothrombin time prolonged	--	827	100	1	0.121	828	100	1	0.121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Serum ferritin increased	--	827	100	0	0	828	100	2	0.242	NE	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Transaminases increased	--	827	100	1	0.121	828	100	0	0	NE	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	827	100	3	0.363	828	100	7	0.845	0,427	Algorithm converged.	0,11	1,657	-0,483	Algorithm converged.	-1,229	NE	0,429	Algorithm converged.	0,111	1,654	0,3423		2,331	Algorithm converged.	0,605	8,981	
		Dehydration	--	827	100	0	0	828	100	3	0.362	NE	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	--	827	100	1	0.121	828	100	0	0	NE	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	827	100	1	0.121	828	100	2	0.242	0,5	Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987	
		Hyponatraemia	--	827	100	0	0	828	100	3	0.362	NE	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	827	100	1	0.121	828	100	1	0.121	1,001	Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001	Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
	Musculoskeletal and connective tissue disorders	--	--	827	100	3	0.363	828	100	3	0.362	1,001	Algorithm converged.	0,201	4,975	0	Algorithm converged.	-0,579	NE	1,001	Algorithm converged.	0,203	4,946	1		0,999	Algorithm converged.	0,202	4,934	
		Arthralgia	--	827	100	0	0	828	100	1	0.121	NE	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Back pain	--	827	100	1	0.121	828	100	0	0	NE	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Limb discomfort	--	827	100	1	0.121	828	100	0	0	NE	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Musculoskeletal pain	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Myalgia	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pain in extremity	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	827	100	4	0,484	828	100	6	0,725	0,666		Algorithm converged.	0,187	2,368	-0,241	Algorithm converged.	-0,988	NE	0,667		Algorithm converged.	0,189	2,357	0,7532		1,498	Algorithm converged.	0,424	5,29
		Ageusia	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941
		Dizziness	--	827	100	4	0,484	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,484	Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0621		NE	Algorithm not converged.	NE	NE
		Headache	--	827	100	2	0,242	828	100	3	0,362	0,667		Algorithm converged.	0,111	4	-0,12	Algorithm converged.	-0,649	NE	0,667		Algorithm converged.	0,112	3,984	1		1,498	Algorithm converged.	0,251	8,943
		Presyncope	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Syncope	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pregnancy	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	827	100	2	0,242	828	100	1	0,121	2,005		Algorithm converged.	0,181	22,153	0,121	Algorithm converged.	-0,289	NE	2,002		Algorithm converged.	0,182	22,04	0,6245		0,499	Algorithm converged.	0,045	5,497
		Anxiety	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Depression	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Insomnia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	13	1,572	828	100	15	1,812	0,866	Algorithm converged.	0,409	1,831	-0,24	Algorithm converged.	-1,482	NE	0,868	Algorithm converged.	0,415	1,812	0,7055		1,152	Algorithm converged.	0,552	2,407	
	Acute respiratory failure	--	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Bronchospasm	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cough	--	--	827	100	4	0,484	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,484	Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0621		NE	Algorithm not converged.	NE	NE
	Dyspnoea	--	--	827	100	5	0,605	828	100	7	0,845	0,713	Algorithm converged.	0,226	2,257	-0,241	Algorithm converged.	-1,058	NE	0,715	Algorithm converged.	0,228	2,244	0,7736		1,398	Algorithm converged.	0,446	4,388	
	Dyspnoea exertional	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Epistaxis	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hypoxia	--	--	827	100	2	0,242	828	100	4	0,483	0,499	Algorithm converged.	0,091	2,734	-0,241	Algorithm converged.	-0,82	NE	0,501	Algorithm converged.	0,092	2,726	0,6869		1,998	Algorithm converged.	0,367	10,876	
	Nasal congestion	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Oropharyngeal pain	--	--	827	100	2	0,242	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,242	Algorithm converged.	-0,093	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
	Productive cough	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Respiratory distress	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Rhinorrhoea	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Skin and subcutaneous tissue disorders	--	--	827	100	2	0,242	828	100	3	0,362	0,667	Algorithm converged.	0,111	4	-0,12	Algorithm converged.	-0,649	NE	0,667	Algorithm converged.	0,112	3,984	1		1,498	Algorithm converged.	0,251	8,943	
	Night sweats	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pruritus	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Rash	--	--	827	100	2	0,242	828	100	2	0,242	1,001	Algorithm converged.	0,141	7,125	0	Algorithm converged.	-0,473	NE	1,001	Algorithm converged.	0,141	7,091	1		0,999	Algorithm converged.	0,141	7,074	
	Vascular disorders	--	--	827	100	1	0,121	828	100	2	0,242	0,5	Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501	Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987	
	Deep vein thrombosis	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Flushing	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Thrombophlebitis superficial	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	Blood and lymphatic system disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Thrombocytopenia		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Thrombocytosis		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	Male	405	48,972	2	0,494	381	46,014	1	0,262	1,886		Algorithm converged.	0,17	20,883	0,231	Algorithm converged.	-0,623	NE	1,881	*	Algorithm converged.	0,171	20,665	1	1	0,531	Algorithm converged.	0,048	5,838
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Palpitations		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	405	48,972	2	0,494	381	46,014	3	0,787	0,625		Algorithm converged.	0,104	3,763	-0,294	Algorithm converged.	-1,413	NE	0,627	*	Algorithm converged.	0,105	3,733	0,6777	0,2202	1,594	Algorithm converged.	0,268	9,49
			Female	422	51,028	7	1,659	447	53,986	3	0,671	2,496		Algorithm converged.	0,641	9,718	0,988	Algorithm converged.	-0,447	NE	2,472	*	Algorithm converged.	0,643	9,495	0,2123	0,405		Algorithm converged.	0,105	1,554
	Abdominal pain upper		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Chronic gastritis		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
		Diarrhoea	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	0,288	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	*	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045	
		Gastroesophageal reflux disease	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
		Nausea	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,5823	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	5	1,185	447	53,986	1	0,224	5,348		Algorithm converged.	0,622	45,964	0,961	Algorithm converged.	-0,16	NE	5,296	*	Algorithm converged.	0,621	45,146	0,1139		0,189	Algorithm converged.	0,022	1,609	
		Peptic ulcer perforation	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Vomiting	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		General disorders and administration site conditions	Male	405	48,972	2	0,494	381	46,014	1	0,262	1,886		Algorithm converged.	0,17	20,883	0,231	Algorithm converged.	-0,623	NE	1,881	*	Algorithm converged.	0,171	20,665	1	0,7132	0,531	Algorithm converged.	0,048	5,838	
			Female	422	51,028	2	0,474	447	53,986	2	0,447	1,06		Algorithm converged.	0,149	7,556	0,027	Algorithm converged.	-0,875	NE	1,059	*	Algorithm converged.	0,15	7,486	1		0,944	Algorithm converged.	0,134	6,672	
		Chest discomfort	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
		Fatigue	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Non-cardiac chest pain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pyrexia	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	405	48,972	5	1,235	381	46,014	11	2,887	0,42		Algorithm converged.	0,145	1,222	-1,653	Algorithm converged.	-3,648	NE	0,428		Algorithm converged.	0,15	1,219	0,1302	0,7158	2,339	Algorithm converged.	0,82	6,668
			Female	422	51,028	2	0,474	447	53,986	7	1,566	0,299		Algorithm converged.	0,062	1,449	-1,092	Algorithm converged.	-2,416	NE	0,303		Algorithm converged.	0,063	1,449	0,1791	3,304	Algorithm converged.	0,69	15,816	
		Bacteraemia	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchitis	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	Male	405	48,972	3	0,741	381	46,014	7	1,837	0,399		Algorithm converged.	0,102	1,553	-1,097	Algorithm converged.	-2,683	NE	0,403		Algorithm converged.	0,105	1,548	0,2115	0,9208	2,48	Algorithm converged.	0,646	9,522
			Female	422	51,028	1	0,237	447	53,986	3	0,671	0,352		Algorithm converged.	0,036	3,393	-0,434	Algorithm converged.	-1,322	NE	0,353		Algorithm converged.	0,037	3,381	0,6248	2,832	Algorithm converged.	0,296	27,121	
		Pneumonia bacterial	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinusitis	Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469		Algorithm converged.	0,042	5,194	-0,278	Algorithm converged.	-1,15	NE	0,47		Algorithm converged.	0,043	5,166	0,6134	1	2,126	Algorithm converged.	0,194	23,35
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tooth abscess	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Urinary tract infection	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Infusion related reaction	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ligament sprain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
	Investigations	--	Male	405	48,972	10	2,469	381	46,014	8	2,1	1,18		Algorithm converged.	0,461	3,023	0,369	Algorithm converged.	-1,718	NE	1,176		Algorithm converged.	0,469	2,948	0,7295	0,5183	0,85	Algorithm converged.	0,339	2,132
			Female	422	51,028	4	0,948	447	53,986	6	1,342	0,703		Algorithm converged.	0,197	2,51	-0,394	Algorithm converged.	-1,806	NE	0,706		Algorithm converged.	0,201	2,485	0,7535		1,416	Algorithm converged.	0,402	4,983

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Activated partial thromboplastin time prolonged	Male	405	48,972	2	0,494	381	46,014	3	0,787	0,625	Algorithm converged.	0,104	3,763	-0,294	Algorithm converged.	-1,413	NE	0,627	Algorithm converged.	0,105	3,733	0,6777	0,6973	1,594	Algorithm converged.	0,268	9,49
			Female	422	51,028	2	0,474	447	53,986	2	0,447	1,06	Algorithm converged.	0,149	7,556	0,027	Algorithm converged.	-0,875	NE	1,059	Algorithm converged.	0,15	7,486	1		0,944	Algorithm converged.	0,134	6,672
		Alanine aminotransferase increased	Male	405	48,972	3	0,741	381	46,014	2	0,525	1,414	Algorithm converged.	0,235	8,51	0,216	Algorithm converged.	-0,89	NE	1,411	Algorithm converged.	0,237	8,399	1	0,5115	0,709	Algorithm converged.	0,119	4,218
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529	Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53	Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746
		Aspartate aminotransferase increased	Male	405	48,972	1	0,247	381	46,014	0	0	NE	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	Algorithm not converged.	NE	NE	1	0,2042	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529	Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53	Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746
		Blood creatine phosphokinase increased	Male	405	48,972	2	0,494	381	46,014	1	0,262	1,886	Algorithm converged.	0,17	20,883	0,231	Algorithm converged.	-0,623	NE	1,881	Algorithm converged.	0,171	20,665	1	1	0,531	Algorithm converged.	0,048	5,838
			Female	422	51,028	0	0	447	53,986	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	Male	405	48,972	2	0,494	381	46,014	4	1,05	0,468	Algorithm converged.	0,085	2,569	-0,556	Algorithm converged.	-1,786	NE	0,47	Algorithm converged.	0,087	2,553	0,4383	0,6247	2,126	Algorithm converged.	0,392	11,54
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045
		Fibrin D dimer increased	Male	405	48,972	2	0,494	381	46,014	2	0,525	0,94	Algorithm converged.	0,132	6,71	-0,031	Algorithm converged.	-1,027	NE	0,941	Algorithm converged.	0,133	6,645	1	0,1043	1,063	Algorithm converged.	0,15	7,509
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	Algorithm not converged.	NE	NE	-0,671	Algorithm converged.	-1,428	NE	NE	Algorithm not converged.	NE	NE	0,2498		NE	Algorithm not converged.	NE	NE
		Heart rate decreased	Male	405	48,972	1	0,247	381	46,014	0	0	NE	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	1	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	0	0	447	53,986	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	1	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	0	0	447	53,986	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Prothrombin time prolonged	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	1	1,063	Algorithm converged.	0,067	16,935		
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Serum ferritin increased	Male	405	48,972	0	0	381	46,014	2	0,525	NE	*	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Transaminases increased	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Metabolism and nutrition disorders	--		Male	405	48,972	3	0,741	381	46,014	3	0,787	0,94	Algorithm converged.	0,189	4,687	-0,047	Algorithm converged.	-1,265	NE	0,941	Algorithm converged.	0,191	4,632	1	0,0566	1,063	Algorithm converged.	0,216	5,234		
			Female	422	51,028	0	0	447	53,986	4	0,895	NE	*	Algorithm not converged.	NE	NE	-0,895	Algorithm converged.	-1,768	NE	NE	*	Algorithm not converged.	NE	NE	0,1248	NE	Algorithm not converged.	NE	NE	
		Dehydration	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	Algorithm not converged.	NE	NE	
		Hyperkalaemia	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hypokalaemia	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	0,3246	1,063	Algorithm converged.	0,067	16,935		
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Hyponatraemia	Male	405	48,972	0	0	381	46,014	2	0,525	NE	*	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Type 2 diabetes mellitus	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
Musculoskeletal and connective tissue disorders	--		Male	405	48,972	2	0,494	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,494	Algorithm converged.	-0,189	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	0,0579	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	1	0,237	447	53,986	3	0,671	0,352	Algorithm converged.	0,036	3,393	-0,434	Algorithm converged.	-1,322	NE	0,353	Algorithm converged.	0,037	3,381	0,6248		2,832	Algorithm converged.	0,296	27,121		
		Arthralgia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
		Back pain	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Limb discomfort	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	
		Musculoskeletal pain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
		Myalgia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
		Pain in extremity	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	
		Rhabdomyolysis	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
	Nervous system disorders	--	Male	405	48,972	1	0,247	381	46,014	3	0,787	0,312	Algorithm converged.	0,032	3,011	-0,54	Algorithm converged.	-1,551	NE	0,314	Algorithm converged.	0,033	3,002	0,3594	0,3715	3,189	Algorithm converged.	0,333	30,525		
			Female	422	51,028	3	0,711	447	53,986	3	0,671	1,06	Algorithm converged.	0,213	5,279	0,04	Algorithm converged.	-1,063	NE	1,059	Algorithm converged.	0,215	5,219	1		0,944	Algorithm converged.	0,192	4,652		
		Ageusia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045		

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Dizziness	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	3	0,711	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,711	Algorithm converged.	-0,091	NE	NE	*	Algorithm not converged.	NE	NE	0,1141		NE	Algorithm not converged.	NE	NE
		Headache	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941		Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941		Algorithm converged.	0,059	14,987	1	0,7575	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53		Algorithm converged.	0,048	5,819	1	1,888	Algorithm converged.	0,172	20,746	
		Presyncope	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Syncope	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pregnancy	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	2	0,474	447	53,986	1	0,224	2,124		Algorithm converged.	0,192	23,509	0,25	Algorithm converged.	-0,538	NE	2,118		Algorithm converged.	0,193	23,277	0,6141		0,472	Algorithm converged.	0,043	5,187
		Anxiety	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Depression	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Insomnia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE	
Reproductive system and breast disorders	--		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
Suppressed lactation			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	--		Male	405	48,972	4	0,988	381	46,014	9	2,362	0,412		Algorithm converged.	0,126	1,35	-1,375	Algorithm converged.	-3,178	NE	0,418		Algorithm converged.	0,13	1,346	0,1653	0,0837	2,392	Algorithm converged.	0,743	7,702	
			Female	422	51,028	9	2,133	447	53,986	6	1,342	1,602		Algorithm converged.	0,565	4,539	0,79	Algorithm converged.	-0,953	NE	1,589		Algorithm converged.	0,57	4,426	0,3715		0,629	Algorithm converged.	0,226	1,753	
Acute respiratory failure			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Bronchospasm			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Cough			Male	405	48,972	2	0,494	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,494	Algorithm converged.	-0,189	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	2	0,474	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,474	Algorithm converged.	-0,181	NE	NE	*	Algorithm not converged.	NE	NE	0,2355		NE	Algorithm not converged.	NE	NE	
Dyspnoea			Male	405	48,972	2	0,494	381	46,014	5	1,312	0,373		Algorithm converged.	0,072	1,935	-0,819	Algorithm converged.	-2,15	NE	0,376		Algorithm converged.	0,073	1,928	0,2735	0,2314	2,657	Algorithm converged.	0,519	13,616	
			Female	422	51,028	3	0,711	447	53,986	2	0,447	1,593		Algorithm converged.	0,265	9,581	0,263	Algorithm converged.	-0,749	NE	1,589		Algorithm converged.	0,267	9,462	0,6783	0,629	Algorithm converged.	0,106	3,748		
Dyspnoea exertional			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
Epistaxis			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Hypoxia	Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803		Algorithm converged.	-1,935	NE	0,235		Algorithm converged.	0,026	2,095	0,2041	0,0943	4,252		Algorithm converged.	0,477	37,872	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237		Algorithm not converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE		Algorithm not converged.	NE	NE	NE
		Nasal congestion	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247		Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Oropharyngeal pain	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	2	0,474	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,474		Algorithm converged.	-0,181	NE	NE	*	Algorithm not converged.	NE	NE	0,2355		NE		Algorithm not converged.	NE	NE	NE
		Productive cough	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247		Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Respiratory distress	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
		Rhinorrhoea	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237		Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE		Algorithm not converged.	NE	NE	NE
		Skin and subcutaneous tissue disorders	Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469		Algorithm converged.	0,042	5,194	-0,278		Algorithm converged.	-1,15	NE	0,47		Algorithm converged.	0,043	5,166	0,6134	0,6625	2,126		Algorithm converged.	0,194	23,35	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013		Algorithm converged.	-0,625	NE	1,059		Algorithm converged.	0,066	16,881	1	0,944		Algorithm converged.	0,059	15,045		
		Night sweats	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262		Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Pruritus	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262		Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE		Algorithm not converged.	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Rash	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941	Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	0,9526	1,063	Algorithm converged.	0,067	16,935
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045
	Vascular disorders	--	Male	405	48,972	0	0	381	46,014	2	0,525	NE *	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE *	Algorithm not converged.	NE	NE	0,2346	0,0459	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE *	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Deep vein thrombosis	Male	405	48,972	0	0	381	46,014	1	0,262	NE *	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE *	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Flushing	Male	405	48,972	0	0	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE *	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	Male	405	48,972	0	0	381	46,014	1	0,262	NE *	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE *	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
Age	Blood and lymphatic system disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombocytopenia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombocytosis	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Cardiac disorders	--	18-64	724	87,545	2	0,276	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,276		Algorithm converged.	-0,106	NE	NE	*	Algorithm not converged.	NE	NE	0,2454		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
	Acute myocardial infarction		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Palpitations	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	724	87,545	9	1,243	737	89,01	4	0,543	2,307		Algorithm converged.	0,707	7,524	0,7		Algorithm converged.	-0,265	NE	2,29		Algorithm converged.	0,709	7,404	0,1741	0,0894	0,437		Algorithm converged.	0,135	1,411
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Abdominal pain upper	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic gastritis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Diarrhoea	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508		Algorithm converged.	0,046	5,618	-0,133		Algorithm converged.	-0,596	NE	0,509		Algorithm converged.	0,046	5,601	1		1,965		Algorithm converged.	0,179	21,62
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk													
				n	%	n	%	n	%	n	%	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Gastroesophageal reflux disease	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nausea	18-64	724	87,545	6	0,829	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,829		Algorithm converged.	0,168	NE	NE	*	Algorithm not converged.	NE	NE	0,0147		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Vomiting	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		General disorders and administration site conditions	18-64	724	87,545	4	0,552	737	89,01	3	0,407	1,359		Algorithm converged.	0,303	6,095	0,145		Algorithm converged.	-0,564	NE	1,357		Algorithm converged.	0,305	6,043	0,7236		0,737		Algorithm converged.	0,165	3,28
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Chest discomfort	18-64	724	87,545	2	0,276	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,276	Algorithm converged.	-0,106	NE	NE	*	Algorithm not converged.	NE	NE	0,2454		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fatigue	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	18-64	724	87,545	0	0	737	89,01	3	0,407	NE	*	Algorithm not converged.	NE	NE	-0,407	Algorithm converged.	-0,867	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	
		Hyperbilirubinaemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	18-64	724	87,545	4	0,552	737	89,01	12	1,628	0,336		Algorithm converged.	0,108	1,046	-1,076		Algorithm converged.	-2,137	NE	0,339		Algorithm converged.	0,11	1,047	0,0754	0,9139	2,947		Algorithm converged.	0,955	9,095
			65-74	70	8,464	2	2,857	70	8,454	5	7,143	0,382		Algorithm converged.	0,072	2,041	-4,286		Algorithm converged.	-11,471	NE	0,4		Algorithm converged.	0,08	1,993	0,4411		2,5		Algorithm converged.	0,502	12,457
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571		Algorithm converged.	0,104	23,79
		Bacteraemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchitis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Pneumonia	18-64	724	87,545	2	0,276	737	89,01	8	1,085	0,252	Algorithm converged.	0,053	1,193	-0,809	Algorithm converged.	-1,649	NE	0,254	Algorithm converged.	0,054	1,194	0,1083	0,6464	3,929	Algorithm converged.	0,837	18,441
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1	Algorithm converged.	0,061	16,311	0	Algorithm converged.	-3,931	NE	1	Algorithm converged.	0,064	15,673	1		1	Algorithm converged.	0,064	15,673
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625	Algorithm converged.	0,037	10,565	-1,732	Algorithm converged.	-12,556	NE	0,636	Algorithm converged.	0,042	9,634	1		1,571	Algorithm converged.	0,104	23,79
		Pneumonia bacterial	18-64	724	87,545	0	0	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE *	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	724	87,545	0	0	737	89,01	1	0,136	NE *	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	18-64	724	87,545	0	0	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE *	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinusitis	18-64	724	87,545	0	0	737	89,01	1	0,136	NE *	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1	Algorithm converged.	0,061	16,311	0	Algorithm converged.	-3,931	NE	1	Algorithm converged.	0,064	15,673	1		1	Algorithm converged.	0,064	15,673
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tooth abscess	18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Urinary tract infection	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Injury, poisoning and procedural complications	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	2	2,857	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	2,857	*	Algorithm not converged.	NE	NE	0,4964	*	Algorithm not converged.	NE	NE	0,4964	*	Algorithm not converged.	NE	NE	0,4964	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Infusion related reaction	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	*	Algorithm not converged.	NE	NE	1	*	Algorithm not converged.	NE	NE	1	*	Algorithm not converged.	NE	NE	1	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Ligament sprain	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	*	Algorithm not converged.	NE	NE	1	*	Algorithm not converged.	NE	NE	1	*	Algorithm not converged.	NE	NE	1	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Investigations	18-64	724	87,545	13	1,796	737	89,01	13	1,764	1,018		Algorithm converged.	0,469	2,212	0,032		Algorithm converged.	-1,324	NE	1,018		Algorithm converged.	0,475	2,181	0,9635	0,9999	0,982		Algorithm converged.	0,459	2,105
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0		Algorithm converged.	-3,931	NE	1		Algorithm converged.	0,064	15,673	1		1		Algorithm converged.	0,064	15,673
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Activated partial thromboplastin time prolonged	18-64	724	87,545	4	0,552	737	89,01	5	0,678	0,813	Algorithm converged.	0,218	3,041	-0,126	Algorithm converged.	-0,928	NE	0,814	Algorithm converged.	0,22	3,021	1		1,228	Algorithm converged.	0,331	4,555	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	18-64	724	87,545	3	0,414	737	89,01	4	0,543	0,762	Algorithm converged.	0,17	3,419	-0,128	Algorithm converged.	-0,836	NE	0,763	Algorithm converged.	0,171	3,399	1		1,31	Algorithm converged.	0,294	5,832	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508	Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509	Algorithm converged.	0,046	5,601	1		1,965	Algorithm converged.	0,179	21,62	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	18-64	724	87,545	2	0,276	737	89,01	1	0,136	2,039	Algorithm converged.	0,184	22,533	0,141	Algorithm converged.	-0,325	NE	2,036	Algorithm converged.	0,185	22,403	0,6214		0,491	Algorithm converged.	0,045	5,405	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	18-64	724	87,545	3	0,414	737	89,01	5	0,678	0,609	Algorithm converged.	0,145	2,558	-0,264	Algorithm converged.	-1,019	NE	0,611	Algorithm converged.	0,147	2,546	0,7259		1,637	Algorithm converged.	0,393	6,826	
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Fibrin D dimer increased	18-64	724	87,545	2	0,276	737	89,01	4	0,543	0,508	Algorithm converged.	0,093	2,78	-0,266	Algorithm converged.	-0,92	NE	0,509	Algorithm converged.	0,094	2,77	0,6869		1,965	Algorithm converged.	0,361	10,693
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE *	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Heart rate decreased	18-64	724	87,545	1	0,138	737	89,01	0	0	NE *	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE *	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Prothrombin time prolonged	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Serum ferritin increased	18-64	724	87,545	0	0	737	89,01	2	0,271	NE *	Algorithm not converged.	NE	NE	-0,271	Algorithm converged.	-0,647	NE	NE *	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Transaminases increased	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
	Metabolism and nutrition disorders	--	18-64	724	87,545	3	0,414	737	89,01	2	0,271	1,529		Algorithm converged.	0,255	9,178	0,143		Algorithm converged.	-0,457	NE	1,527		Algorithm converged.	0,256	9,111	0,6843	0,052	0,655		Algorithm converged.	0,11	3,908
			65-74	70	8,464	0	0	70	8,454	4	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714		Algorithm converged.	-11,152	NE	NE	*	Algorithm not converged.	NE	NE	0,1196		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Hyperkalaemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	3	4,286	NE	*	Algorithm not converged.	NE	NE	-4,286		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,2446		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	724	87,545	3	0,414	737	89,01	3	0,407	1,018		Algorithm converged.	0,205	5,061	0,007		Algorithm converged.	-0,649	NE	1,018		Algorithm converged.	0,206	5,027	1		0,982		Algorithm converged.	0,199	4,851
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Arthralgia	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Back pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Limb discomfort	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Musculoskeletal pain	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Myalgia	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pain in extremity	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nervous system disorders	18-64	724	87,545	4	0,552	737	89,01	6	0,814	0,677		Algorithm converged.	0,19	2,409	-0,262		Algorithm converged.	-1,106	NE	0,679		Algorithm converged.	0,192	2,395	0,7532		1,474		Algorithm converged.	0,418	5,2
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Ageusia	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dizziness	18-64	724	87,545	4	0,552	737	89,01	0	0	NE *		Algorithm not converged.	NE	NE	0,552		Algorithm converged.	0,013	NE	NE	*	Algorithm not converged.	NE	NE	0,0601		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	18-64	724	87,545	2	0,276	737	89,01	3	0,407	0,678		Algorithm converged.	0,113	4,068	-0,131		Algorithm converged.	-0,729	NE	0,679		Algorithm converged.	0,114	4,049	1		1,474		Algorithm converged.	0,247	8,793
			65-74	70	8,464	0	0	70	8,454	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Presyncope	18-64	724	87,545	0	0	737	89,01	1	0,136	NE *		Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Syncope	18-64	724	87,545	0	0	737	89,01	1	0,136	NE *		Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Pregnancy, puerperium and perinatal conditions	--		18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pregnancy			18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Psychiatric disorders	--		18-64	724	87,545	2	0,276	737	89,01	1	0,136	2,039		Algorithm converged.	0,184	22,533	0,141	Algorithm converged.	-0,325	NE	2,036		Algorithm converged.	0,185	22,403	0,6214		0,491	Algorithm converged.	0,045	5,405	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Anxiety			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Depression			18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Insomnia			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Suppressed lactation	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	11	1,519	737	89,01	11	1,493	1,018		Algorithm converged.	0,439	2,364	0,027		Algorithm converged.	-1,222	NE	1,018		Algorithm converged.	0,444	2,333	0,9665	0,1566	0,982		Algorithm converged.	0,429	2,252
			65-74	70	8,464	2	2,857	70	8,454	2	2,857	1		Algorithm converged.	0,137	7,305	0		Algorithm converged.	-5,519	NE	1		Algorithm converged.	0,145	6,902	1		1		Algorithm converged.	0,145	6,902
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524		Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchospasm	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cough	18-64	724	87,545	4	0,552	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,552		Algorithm converged.	0,013	NE	NE	*	Algorithm not converged.	NE	NE	0,0601		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspnoea	18-64	724	87,545	4	0,552	737	89,01	4	0,543	1,018		Algorithm converged.	0,254	4,086	0,01		Algorithm converged.	-0,747	NE	1,018	*	Algorithm converged.	0,256	4,055	1	0,1834	0,982		Algorithm converged.	0,247	3,913
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0		Algorithm converged.	-3,931	NE	1	*	Algorithm converged.	0,064	15,673	1		1		Algorithm converged.	0,064	15,673
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524		Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE
		Dyspnoea exertional	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Epistaxis	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	18-64	724	87,545	2	0,276	737	89,01	3	0,407	0,678		Algorithm converged.	0,113	4,068	-0,131		Algorithm converged.	-0,729	NE	0,679	*	Algorithm converged.	0,114	4,049	1		1,474		Algorithm converged.	0,247	8,793
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk			Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Nasal congestion	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Oropharyngeal pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Productive cough	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory distress	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhinorrhoea	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Skin and subcutaneous tissue disorders	--											Algorithm converged.	0,046	5,618	-0,133		Algorithm converged.	-0,596	NE	0,509		Algorithm converged.	0,046	5,601	1	0,1884	1,965		Algorithm converged.	0,179	21,62

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
		Night sweats	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
		Pruritus	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rash	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508		Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509	*	Algorithm converged.	0,046	5,601	1		1,965	Algorithm converged.	0,179	21,62	
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vascular disorders --	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
		Deep vein thrombosis	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Flushing	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Baseline viral load categories	Blood and lymphatic system disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Thrombocytopenia <=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Thrombocytosis <=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84		Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014		Algorithm converged.	-0,795	NE	0,953		Algorithm converged.	0,06	15,179	1		1,049		Algorithm converged.	0,066	16,707
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84		Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Palpitations	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE		
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	210	25,393	2	0,952	209	25,242	1	0,478	2		Algorithm converged.	0,18	22,226	0,474		Algorithm converged.	-1,139	NE	1,99		Algorithm converged.	0,182	21,784	1	0,1889	0,502		Algorithm converged.	0,046	5,498
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	1	1,111	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	1,111		Algorithm converged.	-1,054	NE	NE	*	Algorithm not converged.	NE	NE	0,4225		NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6		Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	4	1,102	346	41,787	3	0,867	1,274		Algorithm converged.	0,283	5,734	0,235		Algorithm converged.	-1,217	NE	1,271		Algorithm converged.	0,287	5,637	1	0,787		Algorithm converged.	0,177	3,49	
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444		Algorithm converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342		NE	NE	NE	NE	
		Abdominal pain upper	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478		Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	
		Chronic gastritis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	1	1,111	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	1,111		Algorithm converged.	-1,054	NE	NE	*	Algorithm not converged.	NE	NE	0,4225		NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Diarrhoea	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0.275	346	41,787	2	0.578	0.475		Algorithm converged.	0.043	5.264	-0.303		Algorithm converged.	-1.266	NE	0.477		Algorithm converged.	0.043	5.232	0.6157		2.098		Algorithm converged.	0.191	23,036
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	<=10 ⁵ copies/mL	210	25,393	1	0.476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476		Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nausea	<=10 ⁵ copies/mL	210	25,393	1	0.476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476		Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8		Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	3	0.826	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.826		Algorithm converged.	-0.105	NE	NE	*	Algorithm not converged.	NE	NE	0.2494		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444	Algorithm not converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342		NE	Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm not converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm not converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10^5 copies/mL	210	25,393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952	Algorithm converged.	-0,361	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,1489	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262	Algorithm converged.	-0,687	NE	1,906		Algorithm converged.	0,174	20,929	1		0,525	Algorithm converged.	0,048	5,759	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chest discomfort	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0.551	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.551		Algorithm converged.	-0.211	NE	NE	*	Algorithm not converged.	NE	NE	0.4996		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fatigue	<=10^5 copies/mL	210	25,393	1	0.476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476		Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10^5 copies/mL	210	25,393	1	0.476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476		Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

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95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pyrexia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8		Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014		Algorithm converged.	-0,795	NE	0,953		Algorithm converged.	0,06	15,179	1		1,049		Algorithm converged.	0,066	16,707
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *	Algorithm not converged.	NE	NE	0,275		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	4	1,914	0,245	Algorithm converged.	0,027	2,213	-1,438		Algorithm converged.	-3,516	NE	0,249		Algorithm converged.	0,028	2,207	0,2154	0,7738	4,019		Algorithm converged.	0,453	35,659
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE *	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	1	0,84	125	15,097	4	3,2	0,256	Algorithm converged.	0,028	2,327	-2,36		Algorithm converged.	-5,854	NE	0,263		Algorithm converged.	0,03	2,316	0,3706		3,808		Algorithm converged.	0,432	33,582
			>10 ⁷ copies/mL	363	43,894	5	1,377	346	41,787	9	2,601	0,523	Algorithm converged.	0,174	1,576	-1,224		Algorithm converged.	-3,285	NE	0,53		Algorithm converged.	0,179	1,564	0,2872		1,888		Algorithm converged.	0,639	5,579
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bacteraemia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *	Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchitis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE *	Algorithm not converged.	NE	NE	-0,478		Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm not converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Pharyngitis streptococcal	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm not converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Pneumonia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	2	0,957	NE	*	Algorithm not converged.	NE	NE	-0,957	*	Algorithm converged.	-2,277	NE	NE	*	Algorithm not converged.	NE	NE	0,2482	0,5416	NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	1	0,84	125	15,097	2	1,6	0,521		Algorithm converged.	0,047	5,824	-0,76		Algorithm converged.	-3,503	NE	0,525		Algorithm converged.	0,048	5,716	1		1,904		Algorithm converged.	0,175	20,723						
			>10 ⁷ copies/mL	363	43,894	3	0,826	346	41,787	5	1,445	0,568		Algorithm converged.	0,135	2,396	-0,619		Algorithm converged.	-2,183	NE	0,572		Algorithm converged.	0,138	2,375	0,4959		1,749		Algorithm converged.	0,421	7,261						
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Pneumonia bacterial	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia viral	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sinusitis	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478		Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014		Algorithm converged.	-0,795	NE	0,953		Algorithm converged.	0,06	15,179	1		1,049		Algorithm converged.	0,066	16,707

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Tooth abscess	<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476		Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Urinary tract infection	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	1	2,222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2,222		Algorithm converged.	-2,085	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Infusion related reaction	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0.275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	1	2.222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2.222		Algorithm converged.	-2.085	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Investigations	--	<=10^5 copies/mL	210	25,393	6	2.857	209	25,242	2	0.957	3,044		Algorithm converged.	0,607	15,259	1,9		Algorithm converged.	-0,711	NE	2,986		Algorithm converged.	0,61	14,624	0,2843	0,1467	0,335		Algorithm converged.	0,068	1,64
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	1	1,111	123	14,855	4	3,252	0,334		Algorithm converged.	0,037	3,042	-2,141		Algorithm converged.	-5,951	NE	0,342		Algorithm converged.	0,039	3,006	0,3993		2,927		Algorithm converged.	0,333	25,746
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	4	3,2	0,256		Algorithm converged.	0,028	2,327	-2,36		Algorithm converged.	-5,854	NE	0,263		Algorithm converged.	0,03	2,316	0,3706		3,808		Algorithm converged.	0,432	33,582
			>10^7 copies/mL	363	43,894	6	1,653	346	41,787	4	1,156	1,437		Algorithm converged.	0,402	5,136	0,497		Algorithm converged.	-1,232	NE	1,43		Algorithm converged.	0,407	5,023	0,7529		0,699		Algorithm converged.	0,199	2,457
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Activated partial thromboplastin time prolonged	<=10^5 copies/mL	210	25,393	2	0,952	209	25,242	1	0,478	2		Algorithm converged.	0,18	22,226	0,474		Algorithm converged.	-1,139	NE	1,99			Algorithm converged.	0,182	21,784	1	0,2272	0,502		Algorithm converged.	0,046	5,498
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6		Algorithm converged.	-3,8	NE	NE	*		Algorithm not converged.	NE	NE	0,4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262		Algorithm converged.	-0,687	NE	1,906			Algorithm converged.	0,174	20,929	1		0,525		Algorithm converged.	0,048	5,759
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	<=10^5 copies/mL	210	25,393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952		Algorithm converged.	-0,361	NE	NE	*		Algorithm not converged.	NE	NE	0,4988	0,2413	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	1	1,111	123	14,855	2	1,626	0,68		Algorithm converged.	0,061	7,614	-0,515		Algorithm converged.	-3,627	NE	0,683			Algorithm converged.	0,063	7,42	1		1,463		Algorithm converged.	0,135	15,891
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8		Algorithm converged.	-2,362	NE	NE	*		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014		Algorithm converged.	-0,795	NE	0,953			Algorithm converged.	0,06	15,179	1		1,049		Algorithm converged.	0,066	16,707
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	<=10^5 copies/mL	210	25,393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952		Algorithm converged.	-0,361	NE	NE	*		Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8		Algorithm converged.	-2,362	NE	NE	*		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*		Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Blood creatine phosphokinase increased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,551		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		C-reactive protein increased	<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	1	0,478	0,995		Algorithm converged.	0,062	16,017	-0,002		Algorithm converged.	-1,322	NE	0,995		Algorithm converged.	0,063	15,806	1	0,3034	1,005		Algorithm converged.	0,063	15,958
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6		Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262		Algorithm converged.	-0,687	NE	1,906		Algorithm converged.	0,174	20,929	1		0,525		Algorithm converged.	0,048	5,759
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fibrin D dimer increased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	2	0,957	NE	*	Algorithm not converged.	NE	NE	-0,957		Algorithm converged.	-2,277	NE	NE	*	Algorithm not converged.	NE	NE	0,2482	0,2329	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8		Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262		Algorithm converged.	-0,687	NE	1,906		Algorithm converged.	0,174	20,929	1		0,525		Algorithm converged.	0,048	5,759
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Heart rate decreased	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm not converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hepatic enzyme increased	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		International normalised ratio increased	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Prothrombin time prolonged	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
		Level		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Serum ferritin increased	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE *	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE *	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Transaminases increased	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,5014	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE *	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm not converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	3	0,826	346	41,787	4	1,156	0,713		Algorithm converged.	0,158	3,207	-0,33	Algorithm converged.	-1,791	NE	0,715		Algorithm converged.	0,161	3,171	0,7192		1,399	Algorithm converged.	0,315	6,205	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953	Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1		1,049	Algorithm converged.	0,066	16,707
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE *	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	2	0,578	NE *	Algorithm not converged.	NE	NE	-0,578	Algorithm converged.	-1,377	NE	NE	Algorithm not converged.	NE	NE	0,2378		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953	Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1		1,049	Algorithm converged.	0,066	16,707
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE *	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	Algorithm not converged.	NE	NE	0,4988	0,2378	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE *	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	0,84	Algorithm converged.	-0,8	NE	NE	Algorithm not converged.	NE	NE	0,4877		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911	Algorithm converged.	0,173	21,175	0,262	Algorithm converged.	-0,687	NE	1,906	Algorithm converged.	0,174	20,929	1		0,525	Algorithm converged.	0,048	5,759

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Arthralgia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	*	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Back pain	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Limb discomfort	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Musculoskeletal pain	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Myalgia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pain in extremity	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Nervous system disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	3	2,4	NE	*	Algorithm not converged.	NE	NE	-2,4	Algorithm converged.	-5,083	NE	NE	*	Algorithm not converged.	NE	NE	0,2474	NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	2	0,578	0,953	Algorithm converged.	0,133	6,802	-0,027	Algorithm converged.	-1,131	NE	0,953	Algorithm converged.	0,135	6,729	1	1,049	Algorithm converged.	0,149	7,407	NE	7,407	
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444	Algorithm converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342	NE	NE	NE	NE	
			<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953	Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1	1,049	Algorithm converged.	0,066	16,707	NE	16,707	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953	Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1	1,049	Algorithm converged.	0,066	16,707	NE	16,707	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,551		Algorithm not converged.	-0,211	NE	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	2	4,444	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	4,444		Algorithm not converged.	-1,577	NE	NE	*	Algorithm not converged.	NE	NE	0,5342		NE	Algorithm not converged.	NE	NE
		Headache	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478		Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6		Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	1	2,222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2,222		Algorithm converged.	-2,085	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Presyncope	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8		Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Syncope	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pregnancy	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	1	0,289	1,911		Algorithm converged.	0,173	21,175	0,262		Algorithm converged.	-0,687	NE	1,906		Algorithm converged.	0,174	20,929	1		0,525		Algorithm converged.	0,048	5,759
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anxiety	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *		Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE *		Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Insomnia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *		Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Suppressed lactation	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	210	25,393	3	1,429	209	25,242	1	0,478	3,014		Algorithm converged.	0,311	29,218	0,95		Algorithm converged.	-0,908	NE	2,986		Algorithm converged.	0,313	28,471	0,6232	0,2777	0,335		Algorithm converged.	0,035	3,194
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	1	1,111	123	14,855	1	0,813	1,371		Algorithm converged.	0,085	22,212	0,298		Algorithm converged.	-2,387	NE	1,367		Algorithm converged.	0,087	21,56	1		0,732		Algorithm converged.	0,046	11,543
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6		Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	9	2,479	346	41,787	10	2,89	0,854		Algorithm converged.	0,343	2,128	-0,411		Algorithm converged.	-2,793	NE	0,858		Algorithm converged.	0,353	2,086	0,7351		1,166		Algorithm converged.	0,479	2,834

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	45	5,441	0	0	25	3,019	1	4	NE	*	Algorithm not converged.	NE	NE	-4	Algorithm converged.	-11,681	NE	NE	*	Algorithm not converged.	NE	NE	0,3571		NE	Algorithm not converged.	NE	NE	
		Acute respiratory failure	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	Algorithm converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchospasm	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cough	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	4	1,102	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	1,102	Algorithm converged.	0,028	NE	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dyspnoea	<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1	0,4062	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	1	1,111	123	14,855	1	0,813	1,371		Algorithm converged.	0,085	22,212	0,298	Algorithm converged.	-2,387	NE	1,367		Algorithm converged.	0,087	21,56	1		0,732	Algorithm converged.	0,046	11,543	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	3	0,826	346	41,787	4	1,156	0,713		Algorithm converged.	0,158	3,207	-0,33	Algorithm converged.	-1,791	NE	0,715		Algorithm converged.	0,161	3,171	0,7192	1,399	Algorithm converged.	0,315	6,205		
			Unknown	45	5,441	0	0	25	3,019	1	4	NE	*	Algorithm not converged.	NE	NE	-4	Algorithm converged.	-11,681	NE	NE	*	Algorithm not converged.	NE	NE	0,3571		NE	Algorithm not converged.	NE	NE	
		Dyspnoea exertional	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Epistaxis	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	210	25,393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952	Algorithm converged.	-0,361	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867	Algorithm converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	0,1157		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nasal congestion	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oropharyngeal pain	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,551	Algorithm converged.	-0,211	NE	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Productive cough	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory distress	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhinorrhoea	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Skin and subcutaneous tissue disorders	--	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476		Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	3	0,867	0,316		Algorithm converged.	0,033	3,051	-0,592		Algorithm converged.	-1,707	NE	0,318		Algorithm converged.	0,033	3,04	0,3623		3,147	Algorithm converged.	0,329	30,113
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Night sweats	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Pruritus	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Rash	<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476		Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	2	0,578	0,475	Algorithm converged.	0,043	5,264	-0,303	Algorithm converged.	-1,266	NE	0,477	Algorithm converged.	0,043	5,232	0,6157		2,098	Algorithm converged.	0,191	23,036
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	2	0,578	0,475	Algorithm converged.	0,043	5,264	-0,303	Algorithm converged.	-1,266	NE	0,477	Algorithm converged.	0,043	5,232	0,6157		2,098	Algorithm converged.	0,191	23,036
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Deep vein thrombosis	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE *	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Flushing	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE *	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Country	Blood and lymphatic system disorders	--	USA	785	94.921	1	0.127	787	95.048	1	0.127	1.003	Algorithm converged.	0.063	16.057	0	Algorithm converged.	-0.352	NE	1.003	Algorithm converged.	0.063	16	1	1	0.997	Algorithm converged.	0.063	15.919	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Thrombocytopenia	USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Thrombocytosis	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	USA	785	94.921	2	0.255	787	95.048	1	0.127	2.008	Algorithm converged.	0.182	22.186	0.128	Algorithm converged.	-0.304	NE	2.005	Algorithm converged.	0.182	22.068	0.6243	1	0.499	Algorithm converged.	0.045	5.489	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction	USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Atrial fibrillation	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Palpitations	USA	785	94.921	1	0.127	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	0.127	Algorithm converged.	-0.122	NE	NE	*	Algorithm not converged.	NE	NE	0.4994		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	USA	785	94.921	8	1.019	787	95.048	6	0.762	1.34	Algorithm converged.	0.463	3.881	0.257	Algorithm converged.	-0.672	NE	1.337	Algorithm converged.	0.466	3.835	0.5881	0.3042	0.748	Algorithm converged.	0.261	2.146	
			MEX	42	5.079	1	2.381	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	2.381	Algorithm converged.	-2.23	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Abdominal pain upper	USA	785	94.921	0	0	787	95.048	1	0.127	NE *	Algorithm not converged.	NE	NE	-0.127	Algorithm converged.	-0.376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5.079	0	0	41	4.952	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Chronic gastritis	USA	785	94.921	0	0	787	95.048	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			MEX	42	5,079	1	2,381	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	2,381	Algorithm converged.	-2,23	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Diarrhoea	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501	*	Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nausea	USA	785	94,921	6	0,764	787	95,048	1	0,127	6,054		Algorithm converged.	0,727	50,402	0,637	Algorithm converged.	-0,021	NE	6,015	*	Algorithm converged.	0,726	49,849	0,0694	1	0,166	Algorithm converged.	0,02	1,378
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	785	94,921	4	0,51	787	95,048	2	0,254	2,01		Algorithm converged.	0,367	11,007	0,255	Algorithm converged.	-0,354	NE	2,005	*	Algorithm converged.	0,368	10,916	0,4518	0,1604	0,499	Algorithm converged.	0,092	2,715
			MEX	42	5,079	0	0	41	4,952	1	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439	Algorithm converged.	-7,161	NE	NE	*	Algorithm not converged.	NE	NE	0,494		NE	Algorithm not converged.	NE	NE
		Chest discomfort	USA	785	94,921	2	0,255	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,255	Algorithm converged.	-0,098	NE	NE	*	Algorithm not converged.	NE	NE	0,2492		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fatigue	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003	*	Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Pyrexia	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	1	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439	Algorithm converged.	-7,161	NE	NE	*	Algorithm not converged.	NE	NE	0,494		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	7	0,892	787	95,048	18	2,287	0,384		Algorithm converged.	0,16	0,926	-1,395	Algorithm converged.	-2,63	NE	0,39		Algorithm converged.	0,164	0,928	0,0271	1	2,565		Algorithm converged.	1,077	6,106
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bacteraemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchitis	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	USA	785	94,921	4	0,51	787	95,048	10	1,271	0,398		Algorithm converged.	0,124	1,274	-0,761	Algorithm converged.	-1,689	NE	0,401		Algorithm converged.	0,126	1,273	0,1776	1	2,494		Algorithm converged.	0,785	7,917
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia bacterial	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Pneumonia viral	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE		
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Sepsis	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Sinusitis	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501		Algorithm converged.	0,046	5,517	1	1	1,995		Algorithm converged.	0,181	21,956				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Tooth abscess	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Urinary tract infection	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Injury, poisoning and procedural complications	USA	785	94,921	2	0,255	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,255	Algorithm converged.	-0,098	NE	NE	*	Algorithm not converged.	NE	NE	0,2492		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Infection related reaction	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Ligament sprain	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Investigations	USA	785	94,921	14	1,783	787	95,048	14	1,779	1,003		Algorithm converged.	0,475	2,117	0,005	Algorithm converged.	-1,303	NE	1,003		Algorithm converged.	0,481	2,089	0,9946	1	0,997		Algorithm converged.	0,479	2,078				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab		
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason
Activated partial thromboplastin time prolonged	USA	785	94,921	4	0,51	787	95,048	5	0,635	0,801	Algorithm converged.	0,214	2,994	-0,126	Algorithm converged.	-0,872	NE	0,802	Algorithm converged.	0,216	2,976	1	1	1,247	Algorithm converged.	0,336	4,626
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
Alanine aminotransferase increased	USA	785	94,921	4	0,51	787	95,048	4	0,508	1,003	Algorithm converged.	0,25	4,023	0,001	Algorithm converged.	-0,702	NE	1,003	Algorithm converged.	0,252	3,994	1	1	0,997	Algorithm converged.	0,25	3,974
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
Aspartate aminotransferase increased	USA	785	94,921	2	0,255	787	95,048	2	0,254	1,003	Algorithm converged.	0,141	7,135	0,001	Algorithm converged.	-0,497	NE	1,003	Algorithm converged.	0,142	7,099	1	1	0,997	Algorithm converged.	0,141	7,063
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
Blood creatine phosphokinase increased	USA	785	94,921	2	0,255	787	95,048	1	0,127	2,008	Algorithm converged.	0,182	22,186	0,128	Algorithm converged.	-0,304	NE	2,005	Algorithm converged.	0,182	22,068	0,6243	1	0,499	Algorithm converged.	0,045	5,489
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
C-reactive protein increased	USA	785	94,921	3	0,382	787	95,048	5	0,635	0,6	Algorithm converged.	0,143	2,519	-0,253	Algorithm converged.	-0,956	NE	0,602	Algorithm converged.	0,144	2,508	0,7259	1	1,662	Algorithm converged.	0,399	6,932
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
Fibrin D dimer increased	USA	785	94,921	2	0,255	787	95,048	5	0,635	0,399	Algorithm converged.	0,077	2,065	-0,381	Algorithm converged.	-1,038	NE	0,401	Algorithm converged.	0,078	2,061	0,4521	1	2,494	Algorithm converged.	0,485	12,815
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
Heart rate decreased	USA	785	94,921	1	0,127	787	95,048	0	0	NE	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	Algorithm not converged.	NE	NE	0,4994	NE	NE	Algorithm not converged.	NE	NE
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
Hepatic enzyme increased	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003	Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003	Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE
International normalised ratio increased	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003	Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003	Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
											Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Prothrombin time prolonged	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Serum ferritin increased	USA	785	94,921	0	0	787	95,048	2	0,254	NE *		Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Transaminases increased	USA	785	94,921	1	0,127	787	95,048	0	0	NE *		Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	785	94,921	3	0,382	787	95,048	7	0,889	0,427		Algorithm converged.	0,11	1,659	-0,507		Algorithm converged.	-1,293	NE	0,43		Algorithm converged.	0,112	1,656	0,3422	1	2,327		Algorithm converged.	0,604	8,968
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	785	94,921	0	0	787	95,048	3	0,381	NE *		Algorithm not converged.	NE	NE	-0,381		Algorithm converged.	-0,812	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperkalaemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE *		Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127		Algorithm converged.	-0,558	NE	0,501		Algorithm converged.	0,046	5,517	1	1	1,995		Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	785	94,921	0	0	787	95,048	3	0,381	NE *		Algorithm not converged.	NE	NE	-0,381		Algorithm converged.	-0,812	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE *		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	USA	785	94,921	3	0,382	787	95,048	3	0,381	1,003		Algorithm converged.	0,202	4,982	0,001		Algorithm converged.	-0,609	NE	1,003		Algorithm converged.	0,203	4,952	1	1	0,997		Algorithm converged.	0,202	4,927

Test for interaction based on RR (Log-binomial regression).

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If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Arthralgia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Back pain	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Limb discomfort	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Musculoskeletal pain	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Myalgia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Pain in extremity	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Rhabdomyolysis	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
	Nervous system disorders	--	USA	785	94,921	4	0,51	787	95,048	6	0,762	0,667		Algorithm converged.	0,187	2,372	-0,253		Algorithm converged.	-1,039	NE	0,668		Algorithm converged.	0,189	2,359	0,7531	1	1,496		Algorithm converged.	0,424	5,281				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	
		Ageusia	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0		Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997		Algorithm converged.	0,063	15,919				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Dizziness	USA	785	94,921	4	0,51	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,51	Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0619		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Headache	USA	785	94,921	2	0,255	787	95,048	3	0,381	0,668		Algorithm converged.	0,111	4,006	-0,126	Algorithm converged.	-0,683	NE	0,668		Algorithm converged.	0,112	3,989	1	1	1,496	Algorithm converged.	0,251	8,93
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Presyncope	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Syncope	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Pregnancy, puerperium and perinatal conditions	--		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Pregnancy		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Psychiatric disorders	--		USA	785	94,921	2	0,255	787	95,048	1	0,127	2,008		Algorithm converged.	0,182	22,186	0,128	Algorithm converged.	-0,304	NE	2,005		Algorithm converged.	0,182	22,068	0,6243	1	0,499	Algorithm converged.	0,045	5,489
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Anxiety		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Depression		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Insomnia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders	--		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
Suppressed lactation			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	--		USA	785	94,921	12	1,529	787	95,048	15	1,906	0,799		Algorithm converged.	0,372	1,718	-0,377	Algorithm converged.	-1,662	NE	0,802		Algorithm converged.	0,378	1,702	0,5649	0,2112	1,247		Algorithm converged.	0,587	2,646			
			MEX	42	5,079	1	2,381	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	2,381	Algorithm converged.	-2,23	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE
Acute respiratory failure			USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	NE	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
Bronchospasm			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
Cough			USA	785	94,921	4	0,51	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,51	Algorithm converged.	0,011	NE	NE	*	Algorithm not converged.	NE	NE	0,0619		NE		Algorithm not converged.	NE	NE	NE	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
Dyspnoea			USA	785	94,921	4	0,51	787	95,048	7	0,889	0,571		Algorithm converged.	0,166	1,957	-0,38	Algorithm converged.	-1,204	NE	0,573		Algorithm converged.	0,168	1,949	0,5474	0,1719	1,746		Algorithm converged.	0,513	5,939			
			MEX	42	5,079	1	2,381	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	2,381	Algorithm converged.	-2,23	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE
Dyspnoea exertional			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
Epistaxis			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Hypoxia	USA	785	94,921	2	0,255	787	95,048	4	0,508	0,5		Algorithm converged.	0,091	2,738	-0,253		Algorithm converged.	-0,863	NE	0,501	*	Algorithm converged.	0,092	2,729	0,6869	1	1,995		Algorithm converged.	0,366	10,86
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Nasal congestion	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Oropharyngeal pain	USA	785	94,921	2	0,255	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,255		Algorithm converged.	-0,098	NE	NE	*	Algorithm not converged.	NE	NE	0,2492		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Productive cough	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Respiratory distress	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Rhinorrhoea	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
	Skin and subcutaneous tissue disorders	--	USA	785	94,921	2	0,255	787	95,048	3	0,381	0,668		Algorithm converged.	0,111	4,006	-0,126		Algorithm converged.	-0,683	NE	0,668	*	Algorithm converged.	0,112	3,989	1	1	1,496		Algorithm converged.	0,251	8,93
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Night sweats	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	
		Pruritus	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Rash	USA	785	94,921	2	0,255	787	95,048	2	0,254	1,003		Algorithm converged.	0,141	7,135	0,001	Algorithm converged.	-0,497	NE	1,003	Algorithm converged.	0,142	7,099	1	1	0,997	Algorithm converged.	0,141	7,063	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		NE	Algorithm not converged.	NE	NE	NE		
	Vascular disorders --		USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501	Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		NE	Algorithm not converged.	NE	NE	NE		
	Deep vein thrombosis		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		NE	Algorithm not converged.	NE	NE	NE		
	Flushing		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		NE	Algorithm not converged.	NE	NE	NE		
	Thrombophlebitis superficial		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*		NE	Algorithm not converged.	NE	NE	NE		

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Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	Cardiac disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Acute myocardial infarction	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Non-cardiac chest pain	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Pyrexia	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941	
		Cholecystitis acute	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	827	100	4	0,484	828	100	16	1,932	0,247		Algorithm converged.	0,082	0,741	-1,449	Algorithm converged.	-2,499	NE	0,25		Algorithm converged.	0,084	0,746	0,0113		3,995	Algorithm converged.	1,341	11,899	
		Bacteraemia	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		COVID-19	--	--	827	100	1	0,121	828	100	7	0,845	0,142		Algorithm converged.	0,017	1,157	-0,724	Algorithm converged.	-1,392	NE	0,143		Algorithm converged.	0,018	1,16	0,0697		6,992	Algorithm converged.	0,862	56,7
		COVID-19 pneumonia	--	--	827	100	1	0,121	828	100	3	0,362	0,333		Algorithm converged.	0,035	3,207	-0,241	Algorithm converged.	-0,714	NE	0,334		Algorithm converged.	0,035	3,202	0,6245		2,996	Algorithm converged.	0,312	28,747
		Pneumonia	--	--	827	100	3	0,363	828	100	6	0,725	0,499		Algorithm converged.	0,124	2,001	-0,362	Algorithm converged.	-1,07	NE	0,501		Algorithm converged.	0,126	1,995	0,5066		1,998	Algorithm converged.	0,501	7,96
	Metabolism and nutrition disorders	--	--	827	100	0	0	828	100	4	0,483	NE	*	Algorithm not converged.	NE	NE	-0,483	Algorithm converged.	-0,955	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE	
		Dehydration	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
				827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Type 2 diabetes mellitus	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Dizziness	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941
		Anxiety	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Depression	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	2	0,242	828	100	5	0,604	0,399		Algorithm converged.	0,077	2,063	-0,362	Algorithm converged.	-0,987	NE	0,4		Algorithm converged.	0,078	2,058	0,4521		2,497	Algorithm converged.	0,486	12,834
		Acute respiratory failure	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	827	100	1	0,121	828	100	2	0,242	0,5		Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501		Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987
		Hypoxia	--	827	100	1	0,121	828	100	2	0,242	0,5		Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501		Algorithm converged.	0,045	5,51	1		1,998	Algorithm converged.	0,181	21,987

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Sex	Cardiac disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	0,0888	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
	Non-cardiac chest pain		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
	Pyrexia		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Cholecystitis acute		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Hyperbilirubinaemia		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Infections and infestations	--	Male	405	48,972	3	0,741	381	46,014	9	2,362	0,308		Algorithm converged.	0,083	1,148	-1,621		Algorithm converged.	-3,36	NE	0,314		Algorithm converged.	0,086	1,15	0,0819	0,547	3,189		Algorithm converged.	0,87	11,691			
			Female	422	51,028	1	0,237	447	53,986	7	1,566	0,149		Algorithm converged.	0,018	1,219	-1,329		Algorithm converged.	-2,57	NE	0,151		Algorithm converged.	0,019	1,225	0,07		6,609		Algorithm converged.	0,817	53,486			
			Bacteraemia	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247		Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE		
				Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			COVID-19	Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803		Algorithm converged.	-1,935	NE	0,235		Algorithm converged.	0,026	2,095	0,2041	0,3324	4,252		Algorithm converged.	0,477	37,872		
				Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671		Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498		NE		Algorithm not converged.	NE	NE		
			COVID-19 pneumonia	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941		Algorithm converged.	0,059	15,091	-0,016		Algorithm converged.	-0,721	NE	0,941		Algorithm converged.	0,059	14,987	1	0,2042	1,063		Algorithm converged.	0,067	16,935		
				Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447		Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE		
			Pneumonia	Male	405	48,972	2	0,494	381	46,014	4	1,05	0,468		Algorithm converged.	0,085	2,569	-0,556		Algorithm converged.	-1,786	NE	0,47		Algorithm converged.	0,087	2,553	0,4383	0,937	2,126		Algorithm converged.	0,392	11,54		
				Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21		Algorithm converged.	-0,984	NE	0,53		Algorithm converged.	0,048	5,819	1		1,888		Algorithm converged.	0,172	20,746		
			Pneumonia bacterial	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
				Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			Metabolism and nutrition disorders	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262		Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE		Algorithm not converged.	NE	NE		
				Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671		Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498		NE		Algorithm not converged.	NE	NE		
			Dehydration	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
				Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			Hypokalaemia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
				Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is unreliable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyponatraemia	Male	405	48,972	0	0	381	46,014	1	0,262	NE	* Algorithm not converged.	NE	NE	-0,262	Algorithm not converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Type 2 diabetes mellitus	Male	405	48,972	0	0	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	* Algorithm not converged.	NE	NE	-0,224	Algorithm not converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
	Musculoskeletal and connective tissue disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	0,247	Algorithm not converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	Male	405	48,972	1	0,247	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	0,247	Algorithm not converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	* Algorithm not converged.	NE	NE	0,237	Algorithm not converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
		Dizziness	Male	405	48,972	0	0	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	* Algorithm not converged.	NE	NE	0,237	Algorithm not converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
	Psychiatric disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm not converged.	0,066	16,991	0,013	Algorithm not converged.	-0,625	NE	1,059	*	Algorithm not converged.	0,066	16,881	1	NE	0,944	Algorithm not converged.	0,059	15,045	
		Anxiety	Male	405	48,972	0	0	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	* Algorithm not converged.	NE	NE	0,237	Algorithm not converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
		Depression	Male	405	48,972	0	0	381	46,014	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	* Algorithm not converged.	NE	NE	-0,224	Algorithm not converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If $np < 5$ in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Respiratory, thoracic and mediastinal disorders	--	Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233	Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	0,235	Algorithm converged.	0,026	2,095	0,2041	0,4004	4,252	Algorithm converged.	0,477	37,872	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059	Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045	
		Acute respiratory failure	Male	405	48,972	0	0	381	46,014	1	0,262	NE *	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE *	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dyspnoea	Male	405	48,972	0	0	381	46,014	2	0,525	NE *	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	0,0459	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Hypoxia	Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469	Algorithm converged.	0,042	5,194	-0,278	Algorithm converged.	-1,15	NE	0,47	Algorithm converged.	0,043	5,166	0,6134	1	2,126	Algorithm converged.	0,194	23,35	
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Age	Cardiac disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	724	87,545	0	0	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	1	4,762	NE	* Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	Peptic ulcer perforation		18-64	724	87,545	0	0	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	1	4,762	NE	* Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	*	Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pyrexia		18-64	724	87,545	0	0	737	89,01	1	0,136	NE	* Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			\geq 75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	18-64	724	87,545	2	0,276	737	89,01	10	1,357	0,201		Algorithm converged.	0,044	0,922	-1,081		Algorithm converged.	-1,999	NE	0,204		Algorithm converged.	0,045	0,926	0,0379	0,7593	4,912	Algorithm converged.	1,08	22,339
			65-74	70	8,464	1	1,429	70	8,454	5	7,143	0,188		Algorithm converged.	0,021	1,656	-5,714		Algorithm converged.	-12,357	NE	0,2		Algorithm converged.	0,024	1,668	0,2086		5	Algorithm converged.	0,599	41,711
			\geq 75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571	Algorithm converged.	0,104	23,79
			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	724	87,545	0	0	737	89,01	5	0,678	NE	*	Algorithm not converged.	NE	NE	-0,678		Algorithm converged.	-1,271	NE	NE	*	Algorithm not converged.	NE	NE	0,0621		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	2	2,857	0,493		Algorithm converged.	0,044	5,562	-1,429		Algorithm converged.	-6,22	NE	0,5		Algorithm converged.	0,046	5,389	1		2	Algorithm converged.	0,186	21,556
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	2	2,857	0,493		Algorithm converged.	0,044	5,562	-1,429		Algorithm converged.	-6,22	NE	0,5		Algorithm converged.	0,046	5,389	1		2	Algorithm converged.	0,186	21,556

Test for interaction based on RR (Log-binomial regression).

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If $n_p < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			\geq 75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	18-64	724	87,545	2	0,276	737	89,01	4	0,543	0,508		Algorithm converged.	0,093	2,78	-0,266		Algorithm converged.	-0,92	NE	0,509		Algorithm converged.	0,094	2,77	0,6869	0,6611	1,965	Algorithm converged.	0,361	10,693
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571	Algorithm converged.	0,104	23,79
		Pneumonia bacterial	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			\geq 75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE			
	Musculoskeletal and connective tissue disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dizziness	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
	Psychiatric disorders	--	65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anxiety	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p < 5$ in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	1	0,138	737	89,01	4	0,543	0,253		Algorithm converged.	0,028	2,273	-0,405		Algorithm converged.	-1	NE	0,254		Algorithm converged.	0,029	2,271	0,3742	0,1587	3,929		Algorithm converged.	0,44	35,072
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508		Algorithm converged.	0,046	5,618	-0,133		Algorithm converged.	-0,596	NE	0,509		Algorithm converged.	0,046	5,601	1		1,965		Algorithm converged.	0,179	21,62
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						p-value					
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	NE	NE	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	NE	NE	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
General disorders and administration site conditions	--		<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Non-cardiac chest pain			<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pyrexia			<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Hepatobiliary disorders	--		<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm converged.	0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1		1,049	Algorithm converged.	0,066	16,707		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Cholecystitis acute	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	NE	*	Algorithm not converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
		Hyperbilirubinaemia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^7 copies/mL	363	43.894	1	0,275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	NE	*	Algorithm not converged.	NE	NE	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
		Infections and infestations	<=10^5 copies/mL	210	25.393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	NE	*	Algorithm not converged.	NE	NE	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	2	1,626	NE	*	Algorithm not converged.	NE	NE	-1,626	NE	*	Algorithm not converged.	NE	NE	-3,861	NE	NE	*	Algorithm not converged.	NE	NE	0,5097	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	5	4	NE	*	Algorithm not converged.	NE	NE	-4	NE	*	Algorithm not converged.	NE	NE	-7,435	NE	NE	*	Algorithm not converged.	NE	NE	0,0603	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	4	1,102	346	41,787	8	2,312	0,471	*	Algorithm not converged.	0,14	1,578	-1,21	NE	*	Algorithm not converged.	0,14	1,568	-3,124	NE	0,477	*	Algorithm not converged.	0,145	1,568	0,2529	2,098		Algorithm not converged.	0,638	6,905
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
		Bacteraemia	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10^7 copies/mL	363	43.894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	NE	*	Algorithm not converged.	NE	NE	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		COVID-19	<=10^5 copies/mL	210	25.393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,707	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	3	0,867	0,316	*	Algorithm converged.	0,033	3,051	-0,592	Algorithm converged.	-1,707	NE	0,318	*	Algorithm converged.	0,033	3,04	0,3623	3,147	NE	Algorithm converged.	0,329	30,113
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	2	0,578	0,475	*	Algorithm converged.	0,043	5,264	-0,303	Algorithm converged.	-1,266	NE	0,477	*	Algorithm converged.	0,043	5,232	0,6157	2,098	NE	Algorithm converged.	0,191	23,036
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pneumonia	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	3	0,826	346	41,787	3	0,867	0,953	*	Algorithm converged.	0,191	4,753	-0,041	Algorithm converged.	-1,39	NE	0,953	*	Algorithm converged.	0,194	4,691	1	1,049	NE	Algorithm converged.	0,213	5,163
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						p-value				
	Metabolism and nutrition disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,1157		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Dizziness	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	1	2.222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2.222	*	Algorithm converged.	-2.085	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41,787	1	0.289	0.953	*	Algorithm converged.	0.059	15.297	-0.014	*	Algorithm converged.	-0.795	NE	0.953	*	Algorithm converged.	0.06	15.179	1		1.049		Algorithm converged.	0.066	16.707
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anxiety	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	*	Algorithm converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	210	25.393	2	0.952	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.952	Algorithm converged.	-0.361	NE	NE	*	Algorithm not converged.	NE	NE	0.4988	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	4	1.156	NE	*	Algorithm not converged.	NE	NE	-1.156	Algorithm converged.	-2.282	NE	NE	*	Algorithm not converged.	NE	NE	0.0562	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	2	0.578	NE	*	Algorithm not converged.	NE	NE	-0.578	Algorithm converged.	-1.377	NE	NE	*	Algorithm not converged.	NE	NE	0.2378	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Dyspnoea	<=10^5 copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476	Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476	Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference			Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Cardiac disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Peptic ulcer perforation		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	General disorders and administration site conditions	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Non-cardiac chest pain		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Pyrexia		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hepatobiliary disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Cholecystitis acute		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hyperbilirubinaemia		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	4	0,51	787	95,048	13	1,652	0,305		Algorithm converged.	0,099	0,939	-1,142		Algorithm converged.	-2,163	NE	0,308		Algorithm converged.	0,101	0,942	0,0478	0,218	3,242	Algorithm converged.	1,062	9,899
			MEX	42	5,079	0	0	41	4,952	3	7,317	NE	*	Algorithm not converged.	NE	NE	-7,317		Algorithm converged.	-15,288	NE	NE	*	Algorithm not converged.	NE	NE	0,116		NE	Algorithm not converged.	NE	NE
		Bacteraemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		COVID-19	USA	785	94,921	1	0,127	787	95,048	4	0,508	0,25		Algorithm converged.	0,028	2,239	-0,381		Algorithm converged.	-0,937	NE	0,251		Algorithm converged.	0,028	2,237	0,3742	0,3051	3,99	Algorithm converged.	0,447	35,617
			MEX	42	5,079	0	0	41	4,952	3	7,317	NE	*	Algorithm not converged.	NE	NE	-7,317		Algorithm converged.	-15,288	NE	NE	*	Algorithm not converged.	NE	NE	0,116		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	USA	785	94,921	1	0,127	787	95,048	3	0,381	0,333		Algorithm converged.	0,035	3,211	-0,254		Algorithm converged.	-0,751	NE	0,334		Algorithm converged.	0,035	3,206	0,6245	1	2,992	Algorithm converged.	0,312	28,705
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	USA	785	94,921	3	0,382	787	95,048	6	0,762	0,499		Algorithm converged.	0,124	2,004	-0,38		Algorithm converged.	-1,126	NE	0,501		Algorithm converged.	0,126	1,997	0,5066	1	1,995	Algorithm converged.	0,501	7,948
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	USA	785	94,921	0	0	787	95,048	4	0,508	NE	*	Algorithm not converged.	NE	NE	-0,508		Algorithm converged.	-1,005	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade ≥ 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyponatraemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Type 2 diabetes mellitus	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Musculoskeletal and connective tissue disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Rhabdomyolysis	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Nervous system disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Dizziness	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Psychiatric disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Anxiety	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Depression	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Respiratory, thoracic and mediastinal disorders	--	USA	785	94,921	2	0,255	787	95,048	5	0,635	0,399	Algorithm converged.	0,077	2,065	-0,381	Algorithm converged.	-1,038	NE	0,401	Algorithm converged.	0,078	2,061	0,4521	1	2,494	Algorithm converged.	0,485	12,815
			MEX	42	5,079	0	0	41	4,952	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute respiratory failure		USA	785	94,921	0	0	787	95,048	2	0,254	NE *	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE *	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Dyspnoea		USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501	Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501	Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hypoxia		USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501	Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501	Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Cardiac disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941
		Non-cardiac chest pain	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Pyrexia	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941
		Cholecystitis acute	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	827	100	3	0,363	828	100	7	0,845	0,427		Algorithm converged.	0,11	1,657	-0,483	Algorithm converged.	-1,229	NE	0,429		Algorithm converged.	0,111	1,654	0,3423		2,331	Algorithm converged.	0,605	8,981
		Bacteraemia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	--	827	100	3	0,363	828	100	6	0,725	0,499		Algorithm converged.	0,124	2,001	-0,362	Algorithm converged.	-1,07	NE	0,501		Algorithm converged.	0,126	1,995	0,5066		1,998	Algorithm converged.	0,501	7,96
	Metabolism and nutrition disorders	--	--	827	100	0	0	828	100	4	0,483	NE	*	Algorithm not converged.	NE	NE	-0,483	Algorithm converged.	-0,955	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
		Dehydration	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia Type 2 diabetes mellitus	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Musculoskeletal and connective tissue disorders	--	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,121	Algorithm converged. Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged. Algorithm not converged.	NE	NE
	Rhabdomyolysis	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,121	Algorithm converged. Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged. Algorithm not converged.	NE	NE
Nervous system disorders	--	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,121	Algorithm converged. Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged. Algorithm not converged.	NE	NE
	Dizziness	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,121	Algorithm converged. Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged. Algorithm not converged.	NE	NE
Psychiatric disorders	--	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged. Algorithm not converged.	0,063	16,034	0	Algorithm converged. Algorithm not converged.	-0,335	NE	1,001		Algorithm converged. Algorithm not converged.	0,063	15,98	1		0,999	Algorithm converged. Algorithm not converged.	0,063	15,941
	Anxiety	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,121	Algorithm converged. Algorithm not converged.	-0,116	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged. Algorithm not converged.	NE	NE
	Depression	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	-0,121	Algorithm converged. Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	1		NE	Algorithm not converged. Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	--	--	--	827	100	2	0,242	828	100	5	0,604	0,399		Algorithm converged. Algorithm not converged.	0,077	2,063	-0,362	Algorithm converged. Algorithm not converged.	-0,987	NE	0,4		Algorithm converged. Algorithm not converged.	0,078	2,058	0,4521		2,497	Algorithm converged. Algorithm not converged.	0,486	12,834
	Acute respiratory failure	--	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	-0,242	Algorithm converged. Algorithm not converged.	-0,576	NE	NE	*	Algorithm not converged. Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged. Algorithm not converged.	NE	NE
	Dyspnoea	--	--	827	100	1	0,121	828	100	2	0,242	0,5		Algorithm converged. Algorithm not converged.	0,045	5,525	-0,121	Algorithm converged. Algorithm not converged.	-0,53	NE	0,501		Algorithm converged. Algorithm not converged.	0,045	5,51	1		1,998	Algorithm converged. Algorithm not converged.	0,181	21,987
	Hypoxia	--	--	827	100	1	0,121	828	100	2	0,242	0,5		Algorithm converged. Algorithm not converged.	0,045	5,525	-0,121	Algorithm converged. Algorithm not converged.	-0,53	NE	0,501		Algorithm converged. Algorithm not converged.	0,045	5,51	1		1,998	Algorithm converged. Algorithm not converged.	0,181	21,987

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade ≥ 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	Cardiac disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Acute myocardial infarction		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Gastrointestinal disorders	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Peptic ulcer perforation		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	General disorders and administration site conditions	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	0,0888	NE	NE	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	NE
	Non-cardiac chest pain		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	NE
	Pyrexia		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Hepatobiliary disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	0,103	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
	Cholecystitis acute		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
	Hyperbilirubinaemia		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	405	48,972	2	0,494	381	46,014	4	1,05	0,468		Algorithm converged.	0,085	2,569	-0,556		Algorithm converged.	-1,786	NE	0,47		Algorithm converged.	0,087	2,553	0,4383	0,841	2,126	Algorithm converged.	0,392	11,54
			Female	422	51,028	1	0,237	447	53,986	3	0,671	0,352		Algorithm converged.	0,036	3,393	-0,434		Algorithm converged.	-1,322	NE	0,353		Algorithm converged.	0,037	3,381	0,6248		2,832	Algorithm converged.	0,296	27,121
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247		Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	2	0,494	381	46,014	4	1,05	0,468		Algorithm converged.	0,085	2,569	-0,556		Algorithm converged.	-1,786	NE	0,47		Algorithm converged.	0,087	2,553	0,4383	0,937	2,126	Algorithm converged.	0,392	11,54
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21		Algorithm converged.	-0,984	NE	0,53		Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262		Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671		Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262		Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224		Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Musculoskeletal and connective tissue disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Rhabdomyolysis		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE
	Dizziness		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059		Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045	
	Anxiety		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE
	Depression		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	0,235		Algorithm converged.	0,026	2,095	0,2041	0,4004	4,252	Algorithm converged.	0,477	37,872	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059		Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045	
	Acute respiratory failure		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Dyspnoea	Male	405	48,972	0	0	381	46,014	2	0,525	NE	*	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	0,0459	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856		NE	Algorithm not converged.	NE	NE
		Hypoxia	Male	405	48,972	1	0,247	381	46,014	2	0,525	0,469		Algorithm converged.	0,042	5,194	-0,278	Algorithm converged.	-1,15	NE	0,47		Algorithm converged.	0,043	5,166	0,6134	1	2,126	Algorithm converged.	0,194	23,35
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade ≥ 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Age	Cardiac disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥ 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥ 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	724	87,545	0	0	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥ 75	33	3,99	0	0	21	2,536	1	4,762	NE	* Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	Peptic ulcer perforation		18-64	724	87,545	0	0	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥ 75	33	3,99	0	0	21	2,536	1	4,762	NE	* Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018	Algorithm converged.	0,064	16,306	0,002	Algorithm converged.	-0,377	NE	1,018	*	Algorithm not converged.	0,064	16,244	1		0,982	Algorithm converged.	0,062	15,676	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥ 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	* Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			≥ 75	33	3,99	0	0	21	2,536	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pyrexia		18-64	724	87,545	0	0	737	89,01	1	0,136	NE	* Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	* Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	18-64	724	87,545	2	0,276	737	89,01	4	0,543	0,508		Algorithm converged.	0,093	2,78	-0,266		Algorithm converged.	-0,92	NE	0,509		Algorithm converged.	0,094	2,77	0,6869	0,4627	1,965		Algorithm converged.	0,361	10,693
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571		Algorithm converged.	0,104	23,79
			18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			18-64	724	87,545	2	0,276	737	89,01	4	0,543	0,508		Algorithm converged.	0,093	2,78	-0,266		Algorithm converged.	-0,92	NE	0,509		Algorithm converged.	0,094	2,77	0,6869	0,6611	1,965		Algorithm converged.	0,361	10,693
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571		Algorithm converged.	0,104	23,79
			18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
	Metabolism and nutrition disorders	--	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm not converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm not converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
		Hypokalaemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm not converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm not converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
		Type 2 diabetes mellitus	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
		Musculoskeletal and connective tissue disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE					
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dizziness	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018	*	Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anxiety	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	1	0,138	737	89,01	4	0,543	0,253		Algorithm converged.	0,028	2,273	-0,405		Algorithm converged.	-1	NE	0,254	*	Algorithm converged.	0,029	2,271	0,3742	0,1587	3,929		Algorithm converged.	0,44	35,072
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271	Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	724	87,545	1	0,138	737	89,01	2	0,271	0,508		Algorithm converged.	0,046	5,618	-0,133	Algorithm converged.	-0,596	NE	0,509		Algorithm converged.	0,046	5,601	1		1,965	Algorithm converged.	0,179	21,62
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			\geq 75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						p-value					
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Acute myocardial infarction	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	1	0,84	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	0,84	*	Algorithm converged.	-0,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4877		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
General disorders and administration site conditions	--		<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Non-cardiac chest pain			<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pyrexia			<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Hepatobiliary disorders	--		<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		0,059	15,297	-0,014	Algorithm converged.	-0,795	NE	0,953	Algorithm converged.	0,06	15,179	1		1,049	Algorithm converged.	0,066	16,707			
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Cholecystitis acute	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0,275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,3139	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	3	2,4	NE	*	Algorithm not converged.	NE	NE	-2,4	Algorithm converged.	-5,083	NE	NE	*	Algorithm not converged.	NE	NE	0,2474	NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	3	0,826	346	41.787	3	0,867	0,953	*	Algorithm converged.	0,191	4,753	-0,041	Algorithm converged.	-1,39	NE	0,953	*	Algorithm not converged.	0,194	4,691	1	1,049		Algorithm converged.	0,213	5,163	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Bacteraemia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0,275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pneumonia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6		Algorithm not converged.	NE	NE	NE	0,4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	3	0,826	346	41,787	3	0,867	0,953		Algorithm not converged.	0,191	4,753	-0,041		Algorithm not converged.	0,194	4,691	1		1,049		Algorithm not converged.	0,213	5,163	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8		Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867		Algorithm not converged.	NE	NE	NE	0,1157		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
		Dehydration	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm not converged.	NE	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Hypokalaemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Hyponatraemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Type 2 diabetes mellitus	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Musculoskeletal and connective tissue disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm not converged.	NE	NE	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Rhabdomyolysis	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm not converged.	-0,264	NE	NE	1	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Nervous system disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	1	2,222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2,222		Algorithm not converged.	-2,085	NE	NE	1	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Dizziness	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	1	2,222	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	2,222		Algorithm not converged.	-2,085	NE	NE	1	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	1	0,289	0,953		Algorithm not converged.	0,059	15,297	-0,014		Algorithm not converged.	-0,795	NE	0,953		Algorithm not converged.	0,06	15,179	1		1,049		Algorithm not converged.	0,066	16,707	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Anxiety	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Depression	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	210	25,393	2	0,952	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,952	*	Algorithm converged.	NE	NE	-0,361	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	4	1,156	NE	*	Algorithm not converged.	NE	NE	-1,156	*	Algorithm converged.	NE	NE	-2,282	NE	NE	*	Algorithm not converged.	NE	NE	0,0562	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
		Acute respiratory failure	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	*	Algorithm not converged.	NE	NE	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378	NE	NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dyspnoea	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

¶ np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade ≥ 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Cardiac disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Peptic ulcer perforation		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	General disorders and administration site conditions	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Non-cardiac chest pain		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Pyrexia		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hepatobiliary disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Cholecystitis acute		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hyperbilirubinaemia		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade \geq 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	3	0,382	787	95,048	7	0,889	0,427		Algorithm converged.	0,11	1,659	-0,507		Algorithm converged.	-1,293	NE	0,43		Algorithm converged.	0,112	1,656	0,3422	1	2,327		Algorithm converged.	0,604	8,968
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bacteraemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	USA	785	94,921	3	0,382	787	95,048	6	0,762	0,499		Algorithm converged.	0,124	2,004	-0,38		Algorithm converged.	-1,126	NE	0,501		Algorithm converged.	0,126	1,997	0,5066	1	1,995		Algorithm converged.	0,501	7,948
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia bacterial	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	USA	785	94,921	0	0	787	95,048	4	0,508	NE	*	Algorithm not converged.	NE	NE	-0,508		Algorithm converged.	-1,005	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade ≥ 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Musculoskeletal and connective tissue disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Rhabdomyolysis		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Nervous system disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Dizziness		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Psychiatric disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,067	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Anxiety		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Depression		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	785	94,921	2	0,255	787	95,048	5	0,635	0,399		Algorithm converged.	0,077	2,065	-0,381	Algorithm converged.	-1,038	NE	0,401		Algorithm converged.	0,078	2,061	0,4521	1	2,494	Algorithm converged.	0,485	12,815
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute respiratory failure		USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk			
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Dyspnoea	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501	Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501	Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501	Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501	Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Gastrointestinal disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1		0,999	Algorithm converged.	0,063	15,941
	Non-cardiac chest pain	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Pyrexia	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Hepatobiliary disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
	Hyperbilirubinaemia	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
Infections and infestations	--	--	827	100	4	0,484	828	100	13	1,57	0,305		Algorithm converged.	0,099	0,938	-1,086	Algorithm converged.	-2,056	NE	0,308		Algorithm converged.	0,101	0,941	0,0479		3,246	Algorithm converged.	1,063	9,914	
	Bacteraemia	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	COVID-19	--	--	827	100	1	0,121	828	100	5	0,604	0,199		Algorithm converged.	0,023	1,709	-0,483	Algorithm converged.	-1,061	NE	0,2		Algorithm converged.	0,023	1,71	0,2179		4,994	Algorithm converged.	0,585	42,653
	COVID-19 pneumonia	--	--	827	100	1	0,121	828	100	3	0,362	0,333		Algorithm converged.	0,035	3,207	-0,241	Algorithm converged.	-0,714	NE	0,334		Algorithm converged.	0,035	3,202	0,6245		2,996	Algorithm converged.	0,312	28,747
	Pneumonia bacterial	--	--	827	100	3	0,363	828	100	5	0,604	0,599		Algorithm converged.	0,143	2,516	-0,241	Algorithm converged.	-0,909	NE	0,601		Algorithm converged.	0,144	2,506	0,7259		1,665	Algorithm converged.	0,399	6,943
Metabolism and nutrition disorders	--	--	827	100	0	0	828	100	4	0,483	NE	*	Algorithm not converged.	NE	NE	-0,483	Algorithm converged.	-0,955	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE	
	Dehydration	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hypokalaemia	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hyponatraemia Type 2 diabetes mellitus	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Musculoskeletal and connective tissue disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Rhabdomyolysis	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
	Nervous system disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Dizziness	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
	Psychiatric disorders	--	--	827	100	1	0,121	828	100	1	0,121	1,001		Algorithm converged.	0,063	16,034	0	Algorithm converged.	-0,335	NE	1,001		Algorithm converged.	0,063	15,98	1	0,999		Algorithm converged.	0,063	15,941	
		Anxiety	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Depression	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	1	0,121	828	100	5	0,604	0,199		Algorithm converged.	0,023	1,709	-0,483	Algorithm converged.	-1,061	NE	0,2		Algorithm converged.	0,023	1,71	0,2179		4,994		Algorithm converged.	0,585	42,653
		Acute respiratory failure	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Dyspnoea	--	827	100	1	0,121	828	100	2	0,242	0,5		Algorithm converged.	0,045	5,525	-0,121	Algorithm converged.	-0,53	NE	0,501		Algorithm converged.	0,045	5,51	1	1,998		Algorithm converged.	0,181	21,987	
		Hypoxia	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Sex	Gastrointestinal disorders	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	0,0888	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
	Non-cardiac chest pain		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE	NE	
	Pyrexia		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hyperbilirubinaemia		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	405	48,972	3	0,741	381	46,014	8	2,1	0,348		Algorithm converged.	0,092	1,321	-1,359	Algorithm converged.	-3,023	NE	0,353		Algorithm converged.	0,094	1,32	0,133	0,684	2,835	Algorithm converged.	0,758	10,606	
			Female	422	51,028	1	0,237	447	53,986	5	1,119	0,21		Algorithm converged.	0,024	1,805	-0,882	Algorithm converged.	-1,961	NE	0,212		Algorithm converged.	0,025	1,806	0,2183		4,72	Algorithm converged.	0,554	40,237	
	Bacteraemia		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	COVID-19		Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	0,235		Algorithm converged.	0,026	2,095	0,2041	0,5457	4,252	Algorithm converged.	0,477	37,872	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941		Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941		Algorithm converged.	0,059	14,987	1	0,2042	1,063	Algorithm converged.	0,067	16,935	
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
		Pneumonia	Male	405	48,972	2	0,494	381	46,014	3	0,787	0,625		Algorithm converged.	0,104	3,763	-0,294	Algorithm converged.	-1,413	NE	0,627		Algorithm converged.	0,105	3,733	0,6777	0,9114	1,594	Algorithm converged.	0,268	9,49	
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53		Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746	
		Pneumonia bacterial	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Metabolism and nutrition disorders	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671	Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498		NE	Algorithm not converged.	NE	NE	
		Dehydration	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Hypokalaemia	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Hyponatraemia	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Musculoskeletal and connective tissue disorders	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Rhabdomyolysis	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm not converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
	Nervous system disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	0,4856	NE	NE	NE	NE
		Dizziness	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	0,4856	NE	NE	NE	NE
	Psychiatric disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	*	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045			
		Anxiety	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	0,4856	NE	NE	NE	NE
		Depression	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	
	Respiratory, thoracic and mediastinal disorders	--	Male	405	48,972	0	0	381	46,014	4	1,05	NE	*	Algorithm not converged.	NE	NE	-1,05	Algorithm converged.	-2,073	NE	NE	*	Algorithm not converged.	NE	NE	0,0548	0,0943	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	*	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045			
		Acute respiratory failure	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	
		Dyspnoea	Male	405	48,972	0	0	381	46,014	2	0,525	NE	*	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	0,0459	NE	NE	NE	NE	NE	
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	NE	NE	
		Hypoxia	Male	405	48,972	0	0	381	46,014	2	0,525	NE	*	Algorithm not converged.	NE	NE	-0,525	Algorithm converged.	-1,251	NE	NE	*	Algorithm not converged.	NE	NE	0,2346	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

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 * indicates convergence problem. Result is unreliable.
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 If np < 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

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ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Age	Gastrointestinal disorders	--	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE		
	Peptic ulcer perforation		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE		
	General disorders and administration site conditions	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018		Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Non-cardiac chest pain		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Pyrexia		18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Hepatobiliary disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Hyperbilirubinaemia		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	

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POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	18-64	724	87,545	2	0,276	737	89,01	7	0,95	0,289		Algorithm converged.	0,06	1,395	-0,674		Algorithm converged.	-1,471	NE	0,291		Algorithm converged.	0,061	1,395	0,1785	0,8024	3,438		Algorithm converged.	0,717	16,495
			65-74	70	8,464	1	1,429	70	8,454	5	7,143	0,188		Algorithm converged.	0,021	1,656	-5,714		Algorithm converged.	-12,357	NE	0,2		Algorithm converged.	0,024	1,668	0,2086		5		Algorithm converged.	0,599	41,711
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571		Algorithm converged.	0,104	23,79
		Bacteraemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19	18-64	724	87,545	0	0	737	89,01	3	0,407	NE	*	Algorithm not converged.	NE	NE	-0,407		Algorithm converged.	-0,867	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	2	2,857	0,493		Algorithm converged.	0,044	5,562	-1,429		Algorithm converged.	-6,22	NE	0,5		Algorithm converged.	0,046	5,389	1		2		Algorithm converged.	0,186	21,556
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19 pneumonia	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	2	2,857	0,493		Algorithm converged.	0,044	5,562	-1,429		Algorithm converged.	-6,22	NE	0,5		Algorithm converged.	0,046	5,389	1		2		Algorithm converged.	0,186	21,556
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	18-64	724	87,545	2	0,276	737	89,01	3	0,407	0,678		Algorithm converged.	0,113	4,068	-0,131		Algorithm converged.	-0,729	NE	0,679		Algorithm converged.	0,114	4,049	1	0,6241	1,474		Algorithm converged.	0,247	8,793
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,565	-1,732		Algorithm converged.	-12,556	NE	0,636		Algorithm converged.	0,042	9,634	1		1,571		Algorithm converged.	0,104	23,79
		Pneumonia bacterial	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Hypokalaemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	*	Algorithm not converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	*	Algorithm not converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Type 2 diabetes mellitus	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Musculoskeletal and connective tissue disorders	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Nervous system disorders	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

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95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dizziness	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	724	87,545	1	0,138	737	89,01	1	0,136	1,018		Algorithm converged.	0,064	16,306	0,002		Algorithm converged.	-0,377	NE	1,018	*	Algorithm converged.	0,064	16,244	1		0,982		Algorithm converged.	0,062	15,676
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anxiety	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138		Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	0	0	737	89,01	4	0,543	NE	*	Algorithm not converged.	NE	NE	-0,543		Algorithm converged.	-1,073	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429		Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762		Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is unreliable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Dyspnoea	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	1,429	Algorithm converged.	-1,351	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271	Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Baseline viral load categories	Gastrointestinal disorders	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Non-cardiac chest pain		<=10^5 copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pyrexia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	<=10^5 copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275		Algorithm converged.	-0,264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	<=10^5 copies/mL	210	25,393	0	0	209	25,242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478		Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	3	2,4	NE	*	Algorithm not converged.	NE	NE	-2,4		Algorithm converged.	-5,083	NE	NE	*	Algorithm not converged.	NE	NE	0,2474		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43,894	4	1,102	346	41,787	8	2,312	0,471		Algorithm converged.	0,14	1,578	-1,21		Algorithm converged.	-3,124	NE	0,477		Algorithm converged.	0,145	1,568	0,2529		2,098		Algorithm converged.	0,638	6,905
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Bacteraemia			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
COVID-19			<=10^5 copies/mL	210	25.393	0	0	209	25.242	1	0.478	NE	*	Algorithm not converged.	NE	NE	-0.478	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4988		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	3	0.867	0.316		0.033	3.051	-0.592	*	Algorithm not converged.	0.033	3.051	-1.707	NE	0.318		0.033	3.04	0.3623		3.147		Algorithm not converged.	0.329	30.113
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
COVID-19 pneumonia			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	2	0.578	0.475		0.043	5.264	-0.303	*	Algorithm not converged.	0.043	5.264	-1.266	NE	0.477		0.043	5.232	0.6157		2.098		Algorithm not converged.	0.191	23.036
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Pneumonia			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	2	1.6	NE	*	Algorithm not converged.	NE	NE	-1.6	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4982		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	3	0.826	346	41.787	3	0.867	0.953		0.191	4.753	-0.041	*	Algorithm not converged.	0.191	4.753	-1.39	NE	0.953		0.194	4.691	1		1.049		Algorithm not converged.	0.213	5.163
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL
		Pneumonia bacterial	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867	*	Algorithm converged.	NE	NE	0,1157		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Hyponatraemia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Type 2 diabetes mellitus	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm converged.	NE	NE	-0.264		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Rhabdomyolysis	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm converged.	NE	NE	-0.264		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Nervous system disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	1	2.222	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	2.222	Algorithm converged.	-2.085	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dizziness	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	1	2.222	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	2.222	Algorithm converged.	-2.085	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	1	0.289	0.953	Algorithm converged.	0.059	15.297	-0.014	Algorithm converged.	-0.795	NE	0.953	Algorithm converged.	0.06	15.179	1		1.049	Algorithm converged.	0.066	16.707			
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Anxiety		<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	Algorithm converged.	-0.264	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Depression	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE		
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476		Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	NE	NE	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	4	1,156	NE	*	Algorithm not converged.	NE	NE	-1,156		Algorithm converged.	NE	NE	-2,282	NE	NE	*	Algorithm not converged.	NE	NE	0,0562		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Acute respiratory failure	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578		Algorithm converged.	NE	NE	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Dyspnoea	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476		Algorithm converged.	NE	NE	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	NE	NE	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm not converged.	NE	NE	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test		Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hypoxia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813		Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289		Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Gastrointestinal disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Peptic ulcer perforation		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	General disorders and administration site conditions	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Non-cardiac chest pain		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Pyrexia		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hepatobiliary disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hyperbilirubinaemia		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Infections and infestations	--	USA	785	94,921	4	0,51	787	95,048	11	1,398	0,361		Algorithm converged.	0,115	1,14	-0,888	Algorithm converged.	-1,848	NE	0,365		Algorithm converged.	0,117	1,14	0,1167	0,2753	2,743	Algorithm converged.	0,877	8,578
			MEX	42	5,079	0	0	41	4,952	2	4,878	NE	*	Algorithm not converged.	NE	NE	-4,878	Algorithm converged.	-11,472	NE	NE	*	Algorithm not converged.	NE	NE	0,241		NE	Algorithm not converged.	NE	NE
	Bacteraemia		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	COVID-19		USA	785	94,921	1	0,127	787	95,048	3	0,381	0,333		Algorithm converged.	0,035	3,211	-0,254	Algorithm converged.	-0,751	NE	0,334		Algorithm converged.	0,035	3,206	0,6245	0,3344	2,992	Algorithm converged.	0,312	28,705

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			MEX	42	5,079	0	0	41	4,952	2	4,878	NE	*	Algorithm not converged.	NE	NE	-4,878	Algorithm converged.	-11,472	NE	NE	*	Algorithm not converged.	NE	NE	0,241		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	USA	785	94,921	1	0,127	787	95,048	3	0,381	0,333		Algorithm converged.	0,035	3,211	-0,254	Algorithm converged.	-0,751	NE	0,334	Algorithm converged.	0,035	3,206	0,6245	1	2,992	Algorithm converged.	0,312	28,705	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	USA	785	94,921	3	0,382	787	95,048	5	0,635	0,6		Algorithm converged.	0,143	2,519	-0,253	Algorithm converged.	-0,956	NE	0,602	Algorithm converged.	0,144	2,508	0,7259	1	1,662	Algorithm converged.	0,399	6,932	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	USA	785	94,921	0	0	787	95,048	4	0,508	NE	*	Algorithm not converged.	NE	NE	-0,508	Algorithm converged.	-1,005	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal and connective tissue disorders	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Rhabdomyolysis	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dizziness	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	USA	785	94,921	1	0,127	787	95,048	1	0,127	1,003		Algorithm converged.	0,063	16,057	0	Algorithm converged.	-0,352	NE	1,003		Algorithm converged.	0,063	16	1	1	0,997	Algorithm converged.	0,063	15,919
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	785	94,921	1	0,127	787	95,048	5	0,635	0,199		Algorithm converged.	0,023	1,711	-0,508	Algorithm converged.	-1,117	NE	0,201		Algorithm converged.	0,023	1,712	0,2179	1	4,987	Algorithm converged.	0,584	42,591
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	USA	785	94,921	1	0,127	787	95,048	2	0,254	0,501		Algorithm converged.	0,045	5,532	-0,127	Algorithm converged.	-0,558	NE	0,501		Algorithm converged.	0,046	5,517	1	1	1,995	Algorithm converged.	0,181	21,956
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Cardiac disorders	--	--	827	100	1	0,12	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	--	827	100	1	0,12	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		COVID-19	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
Sex	Cardiac disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		
	Acute myocardial infarction		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	
	Hepatobiliary disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	
	Cholecystitis acute		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	
	Infections and infestations	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	COVID-19		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Pneumonia		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Age	Cardiac disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Acute myocardial infarction	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Cholecystitis acute	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271	Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	COVID-19	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pneumonia	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	1	0.84	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	0.84	Algorithm converged.	-0.8	NE	NE	*	Algorithm not converged.	NE	NE	0.4877		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	1	0.84	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	0.84	Algorithm converged.	-0.8	NE	NE	*	Algorithm not converged.	NE	NE	0.4877		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Infections and infestations		--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
COVID-19			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pneumonia			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	Algorithm converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Country	Cardiac disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cholecystitis acute		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5,079	0	0	41	4,952	1	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439	Algorithm converged.	-7,161	NE	NE	*	Algorithm not converged.	NE	NE	0,494		NE	Algorithm not converged.	NE	NE	
	COVID-19		USA	785	94,921	0	0	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	1	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439	Algorithm converged.	-7,161	NE	NE	*	Algorithm not converged.	NE	NE	0,494		NE	Algorithm not converged.	NE	NE	
	Pneumonia		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk						Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
All	Infections and infestations	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
		COVID-19	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							
		Hypoxia	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	Infections and infestations	--	Male	405	48,972	0	0	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE *	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
	COVID-19		Male	405	48,972	0	0	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE *	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
	Hypoxia		Male	405	48,972	1	0,247	381	46,014	0	0	NE *	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Age	Infections and infestations	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	COVID-19		18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hypoxia		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956	NE	NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Baseline viral load categories	Infections and infestations	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE *	Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE		
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		COVID-19	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE *	Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE		
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE *	Algorithm not converged.	NE	NE	0.476	Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	363	43.894	0	0	346	41.787	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Hypoxia	<=10^5 copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE *	Algorithm not converged.	NE	NE	0.476	Algorithm converged.	-0.455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE		NE	NE	NE	NE		
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE		NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Infections and infestations	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	COVID-19		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hypoxia		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Cardiac disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Nausea	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vomiting	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cholecystitis acute	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	827	100	5	0,605	828	100	17	2,053	0,29		Algorithm converged.	0,107	0,79	-1,449	Algorithm converged.	-2,55	NE	0,294		Algorithm converged.	0,109	0,794	0,0162		3,396	Algorithm converged.	1,259	9,162
	Bacteraemia	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	COVID-19 pneumonia	--	--	827	100	1	0,121	828	100	7	0,845	0,142		Algorithm converged.	0,017	1,157	-0,724	Algorithm converged.	-1,392	NE	0,143		Algorithm converged.	0,018	1,16	0,0697		6,992	Algorithm converged.	0,862	56,7
	Pneumonia	--	--	827	100	2	0,242	828	100	2	0,242	1,001		Algorithm converged.	0,141	7,125	0	Algorithm converged.	-0,473	NE	1,001		Algorithm converged.	0,141	7,091	1		0,999	Algorithm converged.	0,141	7,074
		--	--	827	100	2	0,242	828	100	8	0,966	0,248		Algorithm converged.	0,053	1,174	-0,724	Algorithm converged.	-1,47	NE	0,25		Algorithm converged.	0,053	1,175	0,1083		3,995	Algorithm converged.	0,851	18,757

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
	Metabolism and nutrition disorders	--	--	827	100	0	0	828	100	4	0,483	NE *	Algorithm not converged.	NE	NE	-0,483	Algorithm converged.	-0,955	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE							
	Dehydration	--	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							
	Hypokalaemia	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
	Hyponatraemia	--	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							
	Musculoskeletal and connective tissue disorders	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							
	Rhabdomyolysis	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							
	Psychiatric disorders	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
	Depression	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	1	0,121	828	100	9	1,087	0,11	Algorithm converged.	0,014	0,872	-0,966	Algorithm converged.	-1,711	NE	0,111	Algorithm converged.	0,014	0,876	0,0211		8,989	Algorithm converged.	1,141	70,792								
	Acute respiratory failure	--	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE							
	Dyspnoea	--	--	827	100	0	0	828	100	3	0,362	NE *	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE							
	Hypoxia	--	--	827	100	1	0,121	828	100	4	0,483	0,249	Algorithm converged.	0,028	2,236	-0,362	Algorithm converged.	-0,891	NE	0,25	Algorithm converged.	0,028	2,235	0,3742		3,995	Algorithm converged.	0,447	35,669								
	Respiratory distress	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Sex	Cardiac disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
	Acute myocardial infarction	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	--		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	
	Nausea	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE
	Peptic ulcer perforation	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
	Vomiting	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	--		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	NE	NE
	Non-cardiac chest pain	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders	--		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE
	Cholecystitis acute	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 18Feb2021

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	405	48,972	3	0,741	381	46,014	11	2,887	0,251		Algorithm converged.	0,069	0,907	-2,146	Algorithm converged.	-4,024	NE	0,257	Algorithm converged.	0,072	0,913	0,0294	0,7603	3,898	Algorithm converged.	1,096	13,864	
			Female	422	51,028	2	0,474	447	53,986	6	1,342	0,35		Algorithm converged.	0,07	1,744	-0,868	Algorithm converged.	-2,12	NE	0,353	Algorithm converged.	0,072	1,74	0,2884		2,832	Algorithm converged.	0,575	13,955	
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	0,235	Algorithm converged.	0,026	2,095	0,2041	0,3324	4,252	Algorithm converged.	0,477	37,872	
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671	Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	1	0,262	0,941		Algorithm converged.	0,059	15,091	-0,016	Algorithm converged.	-0,721	NE	0,941	Algorithm converged.	0,059	14,987	1	0,9526	1,063	Algorithm converged.	0,067	16,935	
			Female	422	51,028	1	0,237	447	53,986	1	0,224	1,059		Algorithm converged.	0,066	16,991	0,013	Algorithm converged.	-0,625	NE	1,059	Algorithm converged.	0,066	16,881	1		0,944	Algorithm converged.	0,059	15,045	
			Male	405	48,972	1	0,247	381	46,014	6	1,575	0,155		Algorithm converged.	0,019	1,291	-1,328	Algorithm converged.	-2,668	NE	0,157	Algorithm converged.	0,019	1,296	0,0617	0,4588	6,378	Algorithm converged.	0,771	52,732	
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529		Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53	Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746	
			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671	Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
Musculoskeletal and connective tissue disorders	--		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm not converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Rhabdomyolysis			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm not converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	--		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm not converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Depression			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm not converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	--		Male	405	48,972	1	0,247	381	46,014	7	1,837	0,132		Algorithm converged.	0,016	1,08	-1,59	Algorithm converged.	-3,023	NE	0,134		Algorithm converged.	0,017	1,087	0,0332	0,5129	7,441		Algorithm converged.	0,92	60,196						
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Acute respiratory failure			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Dyspnoea			Male	405	48,972	0	0	381	46,014	3	0,787	NE	*	Algorithm not converged.	NE	NE	-0,787	Algorithm converged.	-1,675	NE	NE	*	Algorithm not converged.	NE	NE	0,1134	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hypoxia			Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	0,235		Algorithm converged.	0,026	2,095	0,2041	1	4,252		Algorithm converged.	0,477	37,872						
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory distress			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Age	Cardiac disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	Nausea		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	Vomiting		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			>=75	33	3.99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Non-cardiac chest pain	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
		Hepatobiliary disorders	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
		Cholecystitis acute	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
		Infections and infestations	18-64	724	87,545	2	0,276	737	89,01	11	1,493	0,183		Algorithm converged.	0,04	0,828	-1,216		Algorithm converged.	-2,172	NE	0,185		Algorithm converged.	0,041	0,832	0,022	0,3374	5,403		Algorithm converged.	1,202	24,291		
			65-74	70	8,464	1	1,429	70	8,454	5	7,143	0,188		Algorithm converged.	0,021	1,656	-5,714		Algorithm converged.	-12,357	NE	0,2		Algorithm converged.	0,024	1,668	0,2086		5		Algorithm converged.	0,599	41,711		
			>=75	33	3,99	2	6,061	21	2,536	1	4,762	1,29		Algorithm converged.	0,11	15,185	1,299		Algorithm converged.	-10,917	NE	1,273		Algorithm converged.	0,123	13,177	1		0,786		Algorithm converged.	0,076	8,134		
		Bacteraemia	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	*	Algorithm not converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE		Algorithm not converged.	NE	NE	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
		COVID-19	18-64	724	87,545	0	0	737	89,01	4	0,543	NE	*	Algorithm not converged.	NE	NE	-0,543	*	Algorithm not converged.	-1,073	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	3	4,286	0,324		Algorithm converged.	0,033	3,19	-2,857		Algorithm converged.	-8,356	NE	0,333		Algorithm converged.	0,036	3,127	0,6195		3		Algorithm converged.	0,32	28,146		
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE
		COVID-19 pneumonia	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	*	Algorithm not converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE
			65-74	70	8,464	1	1,429	70	8,454	1	1,429	1		Algorithm converged.	0,061	16,311	0		Algorithm converged.	-3,931	NE	1		Algorithm converged.	0,064	15,673	1		1		Algorithm converged.	0,064	15,673		

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

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95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	33	3.99	1	3.03	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	3,03	Algorithm converged.	-2,818	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	18-64	724	87,545	1	0,138	737	89,01	6	0,814	0,169		Algorithm converged.	0,02	1,403	-0,676	Algorithm converged.	-1,379	NE	0,17	*	Algorithm converged.	0,02	1,406	0,1242	0,602	5,894	Algorithm converged.	0,711	48,837
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	1	3,03	21	2,536	1	4,762	0,625		Algorithm converged.	0,037	10,585	-1,732	Algorithm converged.	-12,556	NE	0,636	*	Algorithm converged.	0,042	9,634	1		1,571	Algorithm converged.	0,104	23,79
	Metabolism and nutrition disorders	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	3	4,286	NE	*	Algorithm not converged.	NE	NE	-4,286	Algorithm converged.	-9,03	NE	NE	*	Algorithm not converged.	NE	NE	0,2446		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	1	0,138	737	89,01	6	0,814	0,169		Algorithm converged.	0,02	1,403	-0,676		Algorithm converged.	-1,379	NE	0,17		Algorithm converged.	0,02	1,406	0,1242	0,609	5,894		Algorithm converged.	0,711	48,837
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524		Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspnoea	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524		Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE
		Hypoxia	18-64	724	87,545	1	0,138	737	89,01	3	0,407	0,338		Algorithm converged.	0,035	3,261	-0,269		Algorithm converged.	-0,802	NE	0,339		Algorithm converged.	0,035	3,254	0,6245	0,7734	2,947		Algorithm converged.	0,307	28,266
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Respiratory distress	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Baseline viral load categories	Cardiac disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	1	0.84	125	15.097	0	0	NE	* Algorithm not converged.	NE	NE	0.84	Algorithm converged.	-0.8	NE	NE	* Algorithm not converged.	NE	NE	NE	0.4877		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
		Acute myocardial infarction	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	1	0.84	125	15.097	0	0	NE	* Algorithm not converged.	NE	NE	0.84	Algorithm converged.	-0.8	NE	NE	* Algorithm not converged.	NE	NE	NE	0.4877		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	* Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	* Algorithm not converged.	NE	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	* Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	* Algorithm not converged.	NE	NE	NE	0.488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
		Nausea	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	* Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	* Algorithm not converged.	NE	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Peptic ulcer perforation	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Vomiting	<=10^5 copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10^5 copies/mL	210	25.393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
Hepatobiliary disorders	--		<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE	
				>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
				>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
				>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm not converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE		Algorithm not converged.	NE	NE	NE	
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
Cholecystitis acute			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE	
				>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
				>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
				>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm not converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE		Algorithm not converged.	NE	NE	NE	
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
Infections and infestations	--		<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	2	0.957	NE	*	Algorithm not converged.	NE	NE	-0.957	Algorithm converged.	-2.277	NE	NE	*	Algorithm not converged.	NE	NE	0.2482	0.1821	NE	Algorithm not converged.	NE	NE	NE		
				>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	2	1.626	NE	*	Algorithm not converged.	NE	NE	-1.626	Algorithm converged.	-3.861	NE	NE	*	Algorithm not converged.	NE	NE	0.5097	NE		Algorithm not converged.	NE	NE	NE	
				>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	4	3.2	NE	*	Algorithm not converged.	NE	NE	-3.2	Algorithm converged.	-6.285	NE	NE	*	Algorithm not converged.	NE	NE	0.1224	NE		Algorithm not converged.	NE	NE	NE	
				>10 ⁷ copies/mL	363	43.894	5	1.377	346	41.787	9	2.601	0.523		Algorithm converged.	0.174	1.576	-1.224	Algorithm converged.	-3.285	NE	0.53	Algorithm converged.	0.179	1.564	0.2872	1.888		Algorithm not converged.	0.639	5.579	NE		
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
Bacteraemia			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE	
				>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
				>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
				>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	Algorithm converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	NE	
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		COVID-19	<=10^5 copies/mL	210	25.393	0	0	209	25.242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,707	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	1	0,275	346	41,787	3	0,867	0,316		Algorithm converged.	0,033	3,051	-0,592	Algorithm converged.	-1,707	NE	0,318	*	Algorithm converged.	0,033	3,04	0,3623	3,147	Algorithm converged.	0,329	30,113	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	2	0,578	0,953		Algorithm converged.	0,133	6,802	-0,027	Algorithm converged.	-1,131	NE	0,953	*	Algorithm converged.	0,135	6,729	1	1,049	Algorithm converged.	0,149	7,407	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Pneumonia	<=10^5 copies/mL	210	25.393	0	0	209	25.242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,5409	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	2	0,551	346	41,787	4	1,156	0,474		Algorithm converged.	0,086	2,603	-0,605	Algorithm converged.	-1,965	NE	0,477	*	Algorithm converged.	0,088	2,585	0,4408	2,098	Algorithm converged.	0,387	11,383	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	363	43,894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	Algorithm converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378	NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Dehydration	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
		Hypokalaemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
		Hyponatraemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	*	Algorithm converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm converged.	NE	NE	NE	0,488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	1	0,275	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	0,275	*	Algorithm converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Rhabdomyolysis	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm not converged.	NE	NE	0.488			NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
		Depression	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	*	Algorithm not converged.	NE	NE	0.488			NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	8	2.312	NE	*	Algorithm not converged.	NE	NE	-2.312	*	Algorithm not converged.	NE	NE	0.0031			NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab								Placebo								Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk																			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL														
Acute respiratory failure			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	Algorithm not converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378	NE	NE	NE	NE	NE	NE	NE	NE									
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
Dyspnoea			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE											
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm not converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	Algorithm not converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378	NE	NE	NE	NE	NE	NE	NE	NE									
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
Hypoxia			<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm not converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE											
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm not converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867	Algorithm not converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	0,1157	NE	NE	NE	NE	NE	NE	NE	NE									
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
Respiratory distress			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE											
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm not converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488	NE	NE	NE	NE	NE	NE	NE	NE									
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE										

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk		
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

¶ np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

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ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Cardiac disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Nausea		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Peptic ulcer perforation		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Vomiting		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	General disorders and administration site conditions	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Non-cardiac chest pain		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hepatobiliary disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	5	0,637	787	95,048	14	1,779	0,354		Algorithm converged.	0,127	0,987	-1,142		Algorithm converged.	-2,22	NE	0,358		Algorithm converged.	0,13	0,989	0,062	0,1867	2,793		Algorithm converged.	1,011	7,717
			MEX	42	5,079	0	0	41	4,952	3	7,317	NE	*	Algorithm not converged.	NE	NE	-7,317		Algorithm not converged.	-15,288	NE	NE	*	Algorithm not converged.	NE	NE	0,116		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	1	0,127	787	95,048	4	0,508	0,25		Algorithm converged.	0,028	2,239	-0,381		Algorithm converged.	-0,937	NE	0,251		Algorithm converged.	0,028	2,237	0,3742	0,3051	3,99		Algorithm converged.	0,447	35,617
			MEX	42	5,079	0	0	41	4,952	3	7,317	NE	*	Algorithm not converged.	NE	NE	-7,317		Algorithm not converged.	-15,288	NE	NE	*	Algorithm not converged.	NE	NE	0,116		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	2	0,255	787	95,048	2	0,254	1,003		Algorithm converged.	0,141	7,135	0,001		Algorithm converged.	-0,497	NE	1,003		Algorithm converged.	0,142	7,099	1	1	0,997		Algorithm converged.	0,141	7,063
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	2	0,255	787	95,048	8	1,017	0,249		Algorithm converged.	0,053	1,175	-0,762		Algorithm converged.	-1,546	NE	0,251		Algorithm converged.	0,053	1,177	0,1083	1	3,99		Algorithm converged.	0,85	18,729
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	0	0	787	95,048	4	0,508	NE	*	Algorithm not converged.	NE	NE	-0,508		Algorithm converged.	-1,005	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Musculoskeletal and connective tissue disorders	--		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Rhabdomyolysis			USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Psychiatric disorders	--		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Depression			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Respiratory, thoracic and mediastinal disorders	--		USA	785	94,921	1	0,127	787	95,048	9	1,144	0,11		Algorithm converged.	0,014	0,872	-1,016	Algorithm converged.	-1,8	NE	0,111	*	Algorithm converged.	0,014	0,877	0,0211	1	8,977	Algorithm converged.	1,14	70,689
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Acute respiratory failure			USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Dyspnoea			USA	785	94,921	0	0	787	95,048	3	0,381	NE	*	Algorithm not converged.	NE	NE	-0,381	Algorithm converged.	-0,812	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hypoxia			USA	785	94,921	1	0,127	787	95,048	4	0,508	0,25		Algorithm converged.	0,028	2,239	-0,381	Algorithm converged.	-0,937	NE	0,251	*	Algorithm converged.	0,028	2,237	0,3742	1	3,99	Algorithm converged.	0,447	35,617
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Respiratory distress			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Cardiac disorders	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Nausea	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vomiting	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	--	827	100	0	0	828	100	1	0,121	NE	*	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	827	100	3	0,363	828	100	8	0,966	0,373		Algorithm converged.	0,099	1,412	-0,603	Algorithm converged.	-1,386	NE	0,375		Algorithm converged.	0,1	1,41	0,225		2,663	Algorithm converged.	0,709	10,004
		Bacteraemia	--	827	100	1	0,121	828	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	827	100	2	0,242	828	100	8	0,966	0,248		Algorithm converged.	0,053	1,174	-0,724	Algorithm converged.	-1,47	NE	0,25		Algorithm converged.	0,053	1,175	0,1083		3,995	Algorithm converged.	0,851	18,757
	Metabolism and nutrition disorders	--	--	827	100	0	0	828	100	4	0,483	NE	*	Algorithm not converged.	NE	NE	-0,483	Algorithm converged.	-0,955	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
		Dehydration	--	827	100	0	0	828	100	2	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Hypokalaemia	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	827	100	1	0,121	828	100	0	0	NE *	Algorithm not converged.	NE	NE	0,121	Algorithm converged.	-0,116	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Depression	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	827	100	1	0,121	828	100	9	1,087	0,11	Algorithm converged.	0,014	0,872	-0,966	Algorithm converged.	-1,711	NE	0,111		Algorithm converged.	0,014	0,876	0,0211		8,989	Algorithm converged.	1,141	70,792
		Acute respiratory failure	--	827	100	0	0	828	100	2	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,576	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	827	100	0	0	828	100	3	0,362	NE *	Algorithm not converged.	NE	NE	-0,362	Algorithm converged.	-0,772	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Hypoxia	--	827	100	1	0,121	828	100	4	0,483	0,249	Algorithm converged.	0,028	2,236	-0,362	Algorithm converged.	-0,891	NE	0,25		Algorithm converged.	0,028	2,235	0,3742		3,995	Algorithm converged.	0,447	35,669
		Respiratory distress	--	827	100	0	0	828	100	1	0,121	NE *	Algorithm not converged.	NE	NE	-0,121	Algorithm converged.	-0,357	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Sex	Cardiac disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE
	Acute myocardial infarction		Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Nausea		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE
	Peptic ulcer perforation		Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE
	Vomiting		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE
	General disorders and administration site conditions	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE
	Non-cardiac chest pain		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	1	0,237	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	0,237	Algorithm converged.	-0,227	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4856	NE	NE	Algorithm not converged.	NE
	Hepatobiliary disorders	--	Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE
	Cholecystitis acute		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	405	48,972	2	0,494	381	46,014	6	1,575	0,31	Algorithm converged.	0,062	1,546	-1,081	Algorithm converged.	-2,505	NE	0,314	Algorithm converged.	0,064	1,544	0,1658	0,7245	3,189	Algorithm converged.	0,648	15,703		
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529	Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53	Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746		
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	6	1,575	0,155	Algorithm converged.	0,019	1,291	-1,328	Algorithm converged.	-2,668	NE	0,157	Algorithm converged.	0,019	1,296	0,0617	0,4588	6,378	Algorithm converged.	0,771	52,732		
			Female	422	51,028	1	0,237	447	53,986	2	0,447	0,529	Algorithm converged.	0,048	5,85	-0,21	Algorithm converged.	-0,984	NE	0,53	Algorithm converged.	0,048	5,819	1		1,888	Algorithm converged.	0,172	20,746		
	Metabolism and nutrition disorders	--	Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	3	0,671	NE	*	Algorithm not converged.	NE	NE	-0,671	Algorithm converged.	-1,428	NE	NE	*	Algorithm not converged.	NE	NE	0,2498	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Male	405	48,972	1	0,247	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	0,247	Algorithm converged.	-0,236	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk					Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
Psychiatric disorders	--		Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
Depression			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
Respiratory, thoracic and mediastinal disorders	--		Male	405	48,972	1	0,247	381	46,014	7	1,837	0,132		Algorithm converged.	0,016	1,08	-1,59	Algorithm converged.	-3,023	NE	NE	0,134	Algorithm converged.	0,017	1,087	0,0332	0,5129	7,441		Algorithm converged.	0,92	60,196			
			Female	422	51,028	0	0	447	53,986	2	0,447	NE	*	Algorithm not converged.	NE	NE	-0,447	Algorithm converged.	-1,066	NE	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE			
Acute respiratory failure			Male	405	48,972	0	0	381	46,014	1	0,262	NE	*	Algorithm not converged.	NE	NE	-0,262	Algorithm converged.	-0,776	NE	NE	*	Algorithm not converged.	NE	NE	0,4847	1	NE		Algorithm not converged.	NE	NE			
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE			
Dyspnoea			Male	405	48,972	0	0	381	46,014	3	0,787	NE	*	Algorithm not converged.	NE	NE	-0,787	Algorithm converged.	-1,675	NE	NE	*	Algorithm not converged.	NE	NE	0,1134	NE	NE		Algorithm not converged.	NE	NE			
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
Hypoxia			Male	405	48,972	1	0,247	381	46,014	4	1,05	0,233		Algorithm converged.	0,026	2,097	-0,803	Algorithm converged.	-1,935	NE	NE	0,235	Algorithm converged.	0,026	2,095	0,2041	1	4,252		Algorithm converged.	0,477	37,872			
			Female	422	51,028	0	0	447	53,986	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE			
Respiratory distress			Male	405	48,972	0	0	381	46,014	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE			
			Female	422	51,028	0	0	447	53,986	1	0,224	NE	*	Algorithm not converged.	NE	NE	-0,224	Algorithm converged.	-0,662	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Age	Cardiac disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	Nausea		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	1	4,762	NE	*	Algorithm not converged.	NE	NE	-4,762	Algorithm converged.	-13,87	NE	NE	*	Algorithm not converged.	NE	NE	0,3889		NE	Algorithm not converged.	NE	NE	
	Vomiting		18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is unreliable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	33	3.99	0	0	21	2.536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Non-cardiac chest pain	18-64	724	87.545	1	0.138	737	89.01	0	0	NE	*	Algorithm not converged.	NE	NE	0.138	Algorithm not converged.	-0.132	NE	NE	*	Algorithm not converged.	NE	NE	0.4956	NE		Algorithm not converged.	NE	NE
			65-74	70	8.464	0	0	70	8.454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3.99	0	0	21	2.536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Hepatobiliary disorders	18-64	724	87.545	0	0	737	89.01	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm not converged.	-0.401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			65-74	70	8.464	0	0	70	8.454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3.99	0	0	21	2.536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Cholecystitis acute	18-64	724	87.545	0	0	737	89.01	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm not converged.	-0.401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			65-74	70	8.464	0	0	70	8.454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3.99	0	0	21	2.536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Infections and infestations	18-64	724	87.545	2	0.276	737	89.01	6	0.814	0.337		Algorithm converged.	0.068	1.678	-0.538	Algorithm converged.	-1.291	NE	0.339	Algorithm converged.	0.069	1.676	0.2879	0.6749	2.947	Algorithm converged.	0.597	14.553	
			65-74	70	8.464	0	0	70	8.454	1	1.429	NE	*	Algorithm not converged.	NE	NE	-1.429	Algorithm not converged.	-4.208	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>=75	33	3.99	1	3.03	21	2.536	1	4.762	0.625		Algorithm converged.	0.037	10.565	-1.732	Algorithm converged.	-12.556	NE	0.636	Algorithm converged.	0.042	9.634	1	1.571	Algorithm converged.	0.104	23.79		
		Bacteraemia	18-64	724	87.545	1	0.138	737	89.01	0	0	NE	*	Algorithm not converged.	NE	NE	0.138	Algorithm not converged.	-0.132	NE	NE	*	Algorithm not converged.	NE	NE	0.4956	NE		Algorithm not converged.	NE	NE
			65-74	70	8.464	0	0	70	8.454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3.99	0	0	21	2.536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Pneumonia	18-64	724	87.545	1	0.138	737	89.01	6	0.814	0.169		Algorithm converged.	0.02	1.403	-0.676	Algorithm converged.	-1.379	NE	0.17	Algorithm converged.	0.02	1.406	0.1242	0.602	5.894	Algorithm converged.	0.711	48.837	
			65-74	70	8.464	0	0	70	8.454	1	1.429	NE	*	Algorithm not converged.	NE	NE	-1.429	Algorithm not converged.	-4.208	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>=75	33	3.99	1	3.03	21	2.536	1	4.762	0.625		Algorithm converged.	0.037	10.565	-1.732	Algorithm converged.	-12.556	NE	0.636	Algorithm converged.	0.042	9.634	1	1.571	Algorithm converged.	0.104	23.79		
		Metabolism and nutrition disorders	18-64	724	87.545	0	0	737	89.01	1	0.136	NE	*	Algorithm not converged.	NE	NE	-0.136	Algorithm not converged.	-0.401	NE	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			65-74	70	8.464	0	0	70	8.454	3	4.286	NE	*	Algorithm not converged.	NE	NE	-4.286	Algorithm not converged.	-9.03	NE	NE	*	Algorithm not converged.	NE	NE	0.2446	NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk						Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE			NE	Algorithm not converged.	NE	NE			
		Dehydration	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE			NE	Algorithm not converged.	NE	NE			
		Hypokalaemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429	Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	724	87,545	0	0	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	70	8,464	0	0	70	8,454	2	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-6,76	NE	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	724	87,545	1	0,138	737	89,01	0	0	NE	*	Algorithm not converged.	NE	NE	0,138	Algorithm converged.	-0,132	NE	NE	*	Algorithm not converged.	NE	NE	0,4956		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136	Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	724	87,545	1	0,138	737	89,01	6	0,814	0,169		Algorithm converged.	0,02	1,403	-0,676		Algorithm converged.	-1,379	NE	0,17		Algorithm converged.	0,02	1,406	0,1242	0,609	5,894		Algorithm converged.	0,711	48,837		
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524		Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE	NE	
		Acute respiratory failure	18-64	724	87,545	0	0	737	89,01	2	0,271	NE	*	Algorithm not converged.	NE	NE	-0,271		Algorithm converged.	-0,647	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Dyspnoea	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	2	9,524	NE	*	Algorithm not converged.	NE	NE	-9,524		Algorithm converged.	-22,079	NE	NE	*	Algorithm not converged.	NE	NE	0,1468		NE		Algorithm not converged.	NE	NE	NE	
		Hypoxia	18-64	724	87,545	1	0,138	737	89,01	3	0,407	0,338		Algorithm converged.	0,035	3,261	-0,269		Algorithm converged.	-0,802	NE	0,339		Algorithm converged.	0,035	3,254	0,6245	0,7734	2,947		Algorithm converged.	0,307	28,266		
			65-74	70	8,464	0	0	70	8,454	1	1,429	NE	*	Algorithm not converged.	NE	NE	-1,429		Algorithm not converged.	-4,208	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
		Respiratory distress	18-64	724	87,545	0	0	737	89,01	1	0,136	NE	*	Algorithm not converged.	NE	NE	-0,136		Algorithm converged.	-0,401	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	
			65-74	70	8,464	0	0	70	8,454	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	
			>=75	33	3,99	0	0	21	2,536	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Baseline viral load categories	Cardiac disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	1	0.84	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	0.84	Algorithm converged.	-0.8	NE	NE	*	Algorithm not converged.	NE	NE	0.4877		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	1	0.84	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	0.84	Algorithm converged.	-0.8	NE	NE	*	Algorithm not converged.	NE	NE	0.4877		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	Algorithm converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE	
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nausea	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	1	0.8	NE	*	Algorithm not converged.	NE	NE	-0.8	Algorithm converged.	-2.362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Peptic ulcer perforation			<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Vomiting			<=10 ⁵ copies/mL	210	25,393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
General disorders and administration site conditions	--		<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Non-cardiac chest pain			<=10 ⁵ copies/mL	210	25,393	1	0,476	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	*	Algorithm converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Hepatobiliary disorders	--		<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE	Algorithm not converged.	NE	NE	NE	NE
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Cholecystitis acute			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				>10^7 copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.488	NE	Algorithm not converged.	NE	NE	NE	NE
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Infections and infestations	--		<=10^5 copies/mL	210	25.393	0	0	209	25.242	1	0.478	NE	*	Algorithm not converged.	NE	NE	-0.478	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4988	0.3857	NE	Algorithm not converged.	NE	NE		
				>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
				>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	2	1.6	NE	*	Algorithm not converged.	NE	NE	-1.6	NE	NE	NE	*	Algorithm not converged.	NE	NE	0.4982	NE	Algorithm not converged.	NE	NE		
				>10^7 copies/mL	363	43.894	3	0.826	346	41.787	4	1.156	0.713	NE	*	Algorithm not converged.	0.158	3.207	-0.33	NE	NE	0.715	NE	NE	0.161	3.171	0.7192	1.399	Algorithm not converged.	0.315	6.205	
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Bacteraemia			<=10^5 copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				>10^6 copies/mL - <=10^7 copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
				>10^7 copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275	NE	NE	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	NE	NE
				Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 # np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Pneumonia			<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	1	0,478	NE	*	Algorithm not converged.	NE	NE	-0,478	Algorithm not converged.	-1,414	NE	NE	*	Algorithm not converged.	NE	NE	0,4988	0,5409	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm not converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	2	1,6	NE	*	Algorithm not converged.	NE	NE	-1,6	Algorithm not converged.	-3,8	NE	NE	*	Algorithm not converged.	NE	NE	0,4982		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	2	0,551	346	41,787	4	1,156	0,474	NE	*	Algorithm converged.	0,086	2,803	-0,605	Algorithm converged.	-1,965	NE	0,477	NE	0,088	2,585	0,4408		2,098	Algorithm converged.	0,387	11,383
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Metabolism and nutrition disorders	--		<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	2	0,578	NE	*	Algorithm not converged.	NE	NE	-0,578	Algorithm converged.	-1,377	NE	NE	*	Algorithm not converged.	NE	NE	0,2378		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Dehydration			<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	1	0,8	NE	*	Algorithm not converged.	NE	NE	-0,8	Algorithm converged.	-2,362	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Hypokalaemia			<=10 ⁵ copies/mL	210	25.393	0	0	209	25,242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hyponatraemia	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813		Algorithm not converged.	-2.4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm not converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Muskuloskeletal and connective tissue disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm not converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	1	0.275	346	41.787	0	0	NE	*	Algorithm not converged.	NE	NE	0.275		Algorithm not converged.	-0.264	NE	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289		Algorithm not converged.	-0.855	NE	NE	*	Algorithm not converged.	NE	NE	0.488		NE		Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Depression	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	1	0.289	NE	*	Algorithm not converged.	NE	NE	-0.289	NE	*	Algorithm not converged.	NE	NE	0.488			NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	210	25.393	1	0.476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0.476	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	8	2.312	NE	*	Algorithm not converged.	NE	NE	-2.312	NE	*	Algorithm not converged.	NE	NE	0.0031			NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
		Acute respiratory failure	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	2	0.578	NE	*	Algorithm not converged.	NE	NE	-0.578	NE	*	Algorithm not converged.	NE	NE	0.2378			NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
		Dyspnoea	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10.883	0	0	123	14.855	1	0.813	NE	*	Algorithm not converged.	NE	NE	-0.813	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14.389	0	0	125	15.097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	363	43.894	0	0	346	41.787	2	0.578	NE	*	Algorithm not converged.	NE	NE	-0.578	NE	*	Algorithm not converged.	NE	NE	0.2378			NE	Algorithm not converged.	NE	NE
			Unknown	45	5.441	0	0	25	3.019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Hypoxia	<=10 ⁵ copies/mL	210	25.393	1	0,476	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	0,476	Algorithm not converged.	-0,455	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	1	0,813	NE	*	Algorithm not converged.	NE	NE	-0,813	Algorithm converged.	-2,4	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	3	0,867	NE	*	Algorithm not converged.	NE	NE	-0,867	Algorithm converged.	-1,844	NE	NE	*	Algorithm not converged.	NE	NE	0,1157		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	<=10 ⁵ copies/mL	210	25.393	0	0	209	25.242	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,883	0	0	123	14,855	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,389	0	0	125	15,097	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	363	43,894	0	0	346	41,787	1	0,289	NE	*	Algorithm not converged.	NE	NE	-0,289	Algorithm converged.	-0,855	NE	NE	*	Algorithm not converged.	NE	NE	0,488		NE	Algorithm not converged.	NE	NE	
			Unknown	45	5,441	0	0	25	3,019	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

¶ np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Cardiac disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Nausea		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Peptic ulcer perforation		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Vomiting		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	General disorders and administration site conditions	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Non-cardiac chest pain		USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127	Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Hepatobiliary disorders	--	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	785	94,921	3	0,382	787	95,048	8	1,017	0,374		Algorithm converged.	0,099	1,413	-0,634		Algorithm converged.	-1,457	NE	0,376		Algorithm converged.	0,1	1,412	0,2249	1	2,66	Algorithm converged.	0,708	9,989
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bacteraemia	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	USA	785	94,921	2	0,255	787	95,048	8	1,017	0,249		Algorithm converged.	0,053	1,175	-0,762		Algorithm converged.	-1,546	NE	0,251		Algorithm converged.	0,053	1,177	0,1083	1	3,99	Algorithm converged.	0,85	18,729
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	785	94,921	0	0	787	95,048	4	0,508	NE	*	Algorithm not converged.	NE	NE	-0,508		Algorithm converged.	-1,005	NE	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127		Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	785	94,921	1	0,127	787	95,048	0	0	NE	*	Algorithm not converged.	NE	NE	0,127		Algorithm converged.	-0,122	NE	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is unreliable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Psychiatric disorders	--		USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Depression			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Respiratory, thoracic and mediastinal disorders	--		USA	785	94,921	1	0,127	787	95,048	9	1,144	0,11		Algorithm converged.	0,014	0,872	-1,016	Algorithm converged.	-1,8	NE	0,111		Algorithm converged.	0,014	0,877	0,0211	1	8,977	Algorithm converged.	1,14	70,689
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Acute respiratory failure			USA	785	94,921	0	0	787	95,048	2	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,606	NE	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Dyspnoea			USA	785	94,921	0	0	787	95,048	3	0,381	NE	*	Algorithm not converged.	NE	NE	-0,381	Algorithm converged.	-0,812	NE	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hypoxia			USA	785	94,921	1	0,127	787	95,048	4	0,508	0,25		Algorithm converged.	0,028	2,239	-0,381	Algorithm converged.	-0,937	NE	0,251		Algorithm converged.	0,028	2,237	0,3742	1	3,99	Algorithm converged.	0,447	35,617
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Respiratory distress			USA	785	94,921	0	0	787	95,048	1	0,127	NE	*	Algorithm not converged.	NE	NE	-0,127	Algorithm converged.	-0,376	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	42	5,079	0	0	41	4,952	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is unreliable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 18Feb2021

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Event		Patients		Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	--	--	--	827	100,0	0	0,0	828	100,0	0	0,0

Clinical cut-off: 18Feb2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Event		Patients		Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Sex	--	--	Male	405	49,0	0	0,0	381	46,0	0	0,0
	--	--	Female	422	51,0	0	0,0	447	54,0	0	0,0

Clinical cut-off: 18Feb2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Event		Patients		Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Age	--	--	18-64	724	87,5	0	0,0	737	89,0	0	0,0
	--	--	65-74	70	8,5	0	0,0	70	8,5	0	0,0
	--	--	>=75	33	4,0	0	0,0	21	2,5	0	0,0

Clinical cut-off: 18Feb2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name				Casirivimab/Imdevimab				Placebo			
	SOC	PT	Level	Patients		Event		Patients		Event	
				n	%	n	%	n	%	n	%
Baseline viral load categories	--	--	<=10 ⁵ copies/mL	210	25,4	0	0,0	209	25,2	0	0,0
	--	--	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	90	10,9	0	0,0	123	14,9	0	0,0
	--	--	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	119	14,4	0	0,0	125	15,1	0	0,0
	--	--	>10 ⁷ copies/mL	363	43,9	0	0,0	346	41,8	0	0,0
	--	--	Unknown	45	5,4	0	0,0	25	3,0	0	0,0

Clinical cut-off: 18Feb2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Event		Patients		Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Country	--	--	USA	785	94,9	0	0,0	787	95,0	0	0,0
	--	--	MEX	42	5,1	0	0,0	41	5,0	0	0,0

Clinical cut-off: 18Feb2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

Datenschnitt 18.02.2021 (DCO1)

Verträglichkeit

Outcome

POPULATION: Safety
 ENDPPOINT: All patients
 MODEL: --
 STUDY: R10933-10987-COV-2067
 Template Outcome of Adverse Events

Category of Adverse Events	Casirivimab/Imdevimab (N=827)														Placebo (N=828)															
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														
All	93	59	63.4	1	1.1	24	25.8	1	1.1	7	7.5	1	1.1	0	0.0	126	97	77.0	0	0.0	19	15.1	1	0.8	6	4.8	0	0.0	3	2.4
Grade 1	47	25	53.2	0	0.0	17	36.2	0	0.0	4	8.5	1	2.1	0	0.0	55	39	70.9	0	0.0	12	21.8	0	0.0	2	3.6	0	0.0	2	3.6
Grade 2	30	24	80.0	0	0.0	4	13.3	0	0.0	2	6.7	0	0.0	0	0.0	40	35	87.5	0	0.0	2	5.0	0	0.0	2	5.0	0	0.0	1	2.5
Grade 3	14	9	64.3	1	7.1	3	21.4	0	0.0	1	7.1	0	0.0	0	0.0	27	20	74.1	0	0.0	5	18.5	0	0.0	2	7.4	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
Missing	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																														
All	12	10	83.3	0	0.0	0	0.0	1	8.3	1	8.3	0	0.0	0	0.0	37	33	89.2	0	0.0	2	5.4	1	2.7	1	2.7	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	9	8	88.9	0	0.0	0	0.0	0	0.0	1	11.1	0	0.0	0	0.0	22	19	86.4	0	0.0	2	9.1	0	0.0	1	4.5	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
Missing	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any AESIs																														
All	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Missing	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: 18Feb2021

Program: t-ae-resolved-general.sas
 Output: t16-ae-resolved-general

Datenschnitt 18.02.2021 (DCO1)

Verträglichkeit

Ergänzende Dokumente

Clinical cut-off: 18Feb2021

**Table 2.1: Duration of Follow-up by domain and arm
Safety Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 828)	Casirivimab/ Imdevimab (N = 827)
Efficacy Follow-up (Days)		
Median	29.0	29.0
Safety 1 Follow-up (Days)		
Median	29.0	29.0
Safety 2 Follow-up (Days)		
Median	52.0	56.0

Datenschnitt 19.08.2021 (DCO2)

Übersicht:

Studie COV-2067

Datenschnitt: 19.08.2021 (DCO2)

Wirksamkeit	
Hauptdokumente	
t12-1-eff-resp-tthos-strat	Hospitalization or all-cause death by day 29
t12-1-eff-resp-tthos-unstrat	Hospitalization or all-cause death by day 29 (subgroup)
t12-2-eff-resp-dth29-strat	All-cause death at Day 29
t12-2-eff-resp-dth29-unstrat	All-cause death at Day 29 (subgroup)
t12-3-eff-resp-dth169-strat	All-cause death at Day 169
t12-3-eff-resp-dth169-unstrat	All-cause death at Day 169 (subgroup)
t12-4-eff-resp-tthos2-strat	Hospitalization or all-cause death from day 4 through day 29
t12-4-eff-resp-tthos2-unstrat	Hospitalization or all-cause death from day 4 through day 29(subgroup)
t12-5-eff-resp-tthcvd-strat	Hospitalization or ER visit or all-cause death through day 29
t12-5-eff-resp-tthcvd-unstrat	Hospitalization or ER visit or all-cause death through day 29 (subgroup)
t12-6-eff-resp-hosp-strat	Hospitalization through day 29
t12-6-eff-resp-hosp-unstrat	Hospitalization through day 29(subgroup)
t12-7-eff-resp-er-strat	ER visit through day 29
t12-7-eff-resp-er-unstrat	ER visit through day 29 (subgroup)
t12-8-eff-resp-mecvent-strat	Mechanical ventilation through day 29
t12-8-eff-resp-mecvent-unstrat	Mechanical ventilation through day 29 (subgroup)
t12-9-eff-resp-oxysup-strat	Supplemental oxygen through day 29
t12-9-eff-resp-oxysup-unstrat	Supplemental oxygen through day 29 (subgroup)
t12-10-eff-resp-icu-strat	Admission to ICU through day 29
t12-10-eff-resp-icu-unstrat	Admission to ICU through day 29 (subgroup)
f1-1-km-plot-overall-tsres	Time to COVID-19 symptoms resolution
t13-1-eff-tte-strat-TSRES	Time to COVID-19 symptoms resolution
t14-5-eff-mean-overall-sec19	Time to COVID-19 symptoms resolution
f1-1-km-plot-subgrp-tsres	Time to COVID-19 symptoms resolution
t13-1-eff-tte-unstrat-TSRES	Time to COVID-19 symptoms resolution(subgroup)
PRO	
f2-2-mean-plot-overall-eq5d0206-eq5dbl	Figure 2.2. Line plot of EQ5D02-EQ VAS Score at each visit mFAS
t15-eff-mmmr-overall-eq5d0206	EQ-5D-5L VAS
t14-2-eff-mean-overall-eq5d0206_eq5dbl	EQ-5D-5L VAS
t14-3-eff-mean-overall-preco19h	Return to usual health
t14-4-eff-mean-overall-preco19a	Return to usual activities
f1-2-km-plot-overall-ttdet10	EQ-5D-5L VAS/ MID = 10: time to first deterioration
t13-2-eff-tte-strat-TTDET10	EQ-5D-5L VAS/ MID = 10: time to first deterioration
f1-3-km-plot-overall-ttdets10	EQ-5D-5L VAS/ MID = 10: time to first deterioration - Sensitivity Analysis
t13-3-eff-tte-strat-TTDETS10	EQ-5D-5L VAS/ MID = 10: time to first deterioration - Sensitivity Analysis
f1-4-km-plot-overall-ttimp10	EQ-5D-5L VAS/ MID = 10: time to first improvement
t13-4-eff-tte-strat-TTIMP10	EQ-5D-5L VAS/ MID = 10: time to first improvement
f1-5-km-plot-overall-ttdet15	EQ-5D-5L VAS/ MID = 15: time to first deterioration
t13-5-eff-tte-strat-TTDET15	EQ-5D-5L VAS/ MID = 15: time to first deterioration
f1-5-km-plot-subgrp-ttdet15	EQ-5D-5L VAS/ MID = 15: time to first deterioration
t13-5-eff-tte-unstrat-TTDET15	EQ-5D-5L VAS/ MID = 15: time to first deterioration (subgroup)
f1-6-km-plot-overall-ttdets15	EQ-5D-5L VAS/ MID = 15: time to first deterioration - Sensitivity Analysis
t13-6-eff-tte-strat-TTDETS15	EQ-5D-5L VAS/ MID = 15: time to first deterioration - Sensitivity Analysis
f1-7-km-plot-overall-ttimp15	EQ-5D-5L VAS/ MID = 15: time to first improvement
t13-7-eff-tte-strat-TTIMP15	EQ-5D-5L VAS/ MID = 15: time to first improvement
f1-7-km-plot-subgrp-ttimp15	EQ-5D-5L VAS/ MID = 15: time to first improvement
t13-7-eff-tte-unstrat-ttimp15	EQ-5D-5L VAS/ MID = 15: time to first improvement (subgroup)
f1-8-km-plot-overall-ttrtuh	Return to usual health: Time to 'Yes'
t13-8-eff-tte-strat-TTRTUH	Return to usual health: Time to 'Yes'
f1-8-km-plot-subgrp-ttrtuh	Return to usual health: Time to 'Yes'
t13-8-eff-tte-unstrat-TTRTUH	Return to usual health: Time to 'Yes' (subgroup)
f1-9-km-plot-overall-ttrtua	Return to usual activities: Time to 'Yes'
t13-9-eff-tte-strat-TTRTUA	Return to usual activities: Time to 'Yes'
f1-9-km-plot-subgrp-ttrtua	Return to usual activities: Time to 'Yes'
t13-9-eff-tte-unstrat-TTRTUA	Return to usual activities: Time to 'Yes' (subgroup)
Ergänzende Dokumente	
t1-dstat-subgrp_mfas	Number of patients for each subgroup and category per arm Modified Full Analysis Set
t3-center_mfas	Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm (mFAS Population)

t4-dstat-demo	Demographic and Baseline Characteristics per arm
t5_disposition	Table 5.1. Summary of Overall Patient Disposition
t5_screen	Table 5.2. Number of screened patients and reason for screening failure
t2-dstat-dur_mfas	Duration of Follow-up by domain and arm Modified Full Analysis Set
t21_1	Table 21.1. Concomitant medications day 1 to day 29
t21_2	Table 21.2. Concomitant medications day 1 to day 29 Indication Reason: Treatment of Adverse Even
t21_3	Table 21.3. Concomitant medications day 1 to day 29 Indication Reason: Medical History
t21_4	Table 21.4. Concomitant medications day 1 to day 29 Indication Reason: Other
t21_5	Table 21.5. Concomitant medications day 1 to day 29 Indication Reason: Premedication
t22_1	Table 22.1. Concomitant procedures day 1 to day 29
t22_2	Table 22.2. Concomitant procedures day 1 to day 29 Indication Reason: Medical History
t22_3	Table 22.3. Concomitant procedures day 1 to day 29 Indication Reason: Adverse Event
t22_4	Table 22.4. Concomitant procedures day 1 to day 29 Indication Reason: Disease under study
t22_5	Table 22.5. Concomitant procedures day 1 to day 29 Indication Reason: Other
t23_dstat_risk_factors	Table 23. Summary of Risk Factors for Severe COVID-19
Verträglichkeit	
Hauptdokumente	
t18-1-ae-raw-anyae-saf1	Any AEs
t18-2-ae-raw-anyae-r-saf1	Any AEs (excluding disease related events)
t18-3-ae-raw-toxgrgt3-saf1	AEs Grade ≥ 3
t18-4-ae-raw-toxgtnr3-saf1	AEs Grade ≥ 3 (excluding disease related events)
t18-5-ae-raw-toxgr3-saf1	AEs Grade 3
t18-6-ae-raw-toxgr4-saf1	AEs Grade 4
t18-7-ae-raw-toxgr5-saf1	AEs Grade 5 (AEs leading to death)
t18-8-ae-raw-anysae-saf1	Any SAEs
t18-9-ae-raw-anysaenr-saf1	Any SAEs (excluding disease related events)
t18-10-ae-raw-aeltdis-saf1	AEs leading to treatment discontinuation
AESI	
t18-11-ae-raw-irr-saf1	IRRs through day 4
t18-12-ae-raw-irrg3-saf1	Grade ≥ 3 IRRs through day 4
t18-13-ae-raw-sirr-saf1	Serious IRRs through day 4
t18-14-ae-raw-hyp-saf1	Hypersensitivity through day 29
t18-15-ae-raw-hypge3-saf1	Grade ≥ 3 Hypersensitivity through day 29
t18-16-ae-raw-shyp-saf1	Serious Hypersensitivity through day 29
SOC/PT	
t19-1f-ae-raw-soc-anyae-fs-saf1	Any AEs
t19-2f-ae-raw-soc-anyae-x-fs-saf1	Any AEs (excluding disease related events)
t19-3f-ae-raw-soc-toxgrgt3-fs-saf1	AEs Grade ≥ 3
t19-4f-ae-raw-soc-toxgrgt3x-fs-saf1	AEs Grade ≥ 3 (excluding disease related events)
t19-5f-ae-raw-soc-toxgr3-fs-saf1	AEs Grade 3
t19-6f-ae-raw-soc-toxgr4-fs-saf1	AEs Grade 4
t19-7f-ae-raw-soc-toxgr5-fs-saf1	AEs Grade 5
t19-8f-ae-raw-soc-anysae-fs-saf1	Any SAEs
t19-9f-ae-raw-soc-anysaex-fs-saf1	Any SAEs (excluding disease related events)
t20-1-ae-soc-descriptive-trtdc-saf1	AEs leading to treatment discontinuation
Outcome	
t17-ae-resolved-aesi	Resolved AESI
t16-ae-resolved-general	AE resolved general
Ergänzende Dokumente	
t2-dstat-dur_saf	Duration of Follow-up by domain and arm Safety Analysis Set

Datenschnitt 19.08.2021 (DCO2)

Wirksamkeit

Hauptdokumente

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related hospitalization or all-cause death through day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test			Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	11	0,9	1193	100	40	3,4	0,27	Algorithm converged.	0,14	0,53	-2,43	Algorithm converged.	-3,59	-1,27	0,28	Algorithm converged.	0,14	0,53	<0.0001		3,63	Algorithm converged.	1,87	7,05

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-1-eff-resp-tthos

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related hospitalization or all-cause death through day 29

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Interaction Test			Relative Risk			
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	11	0,9	1193	100	40	3,4	0,27	Algorithm converged.	0,14	0,53	-2,43	Algorithm converged.	-3,59	-1,27	0,28	Algorithm converged.	0,14	0,53	<0.0001		3,63	Algorithm converged.	1,87	7,05
Sex	Male	579	48,6	9	1,6	580	48,6	20	3,4	0,44	Algorithm converged.	0,2	0,98	-1,894	Algorithm converged.	-3,69	-0,1	0,45	Algorithm converged.	0,21	0,98	0,0391	0,0478	2,22	Algorithm converged.	1,02	4,83
	Female	613	51,4	2	0,3	613	51,4	20	3,3	0,1	Algorithm converged.	0,02	0,42	-2,936	Algorithm converged.	-4,41	-1,46	0,1	Algorithm converged.	0,02	0,43	0,0001		10	Algorithm converged.	2,35	42,6
Age	18-64	1043	87,5	7	0,7	1051	88,1	22	2,1	0,32	Algorithm converged.	0,13	0,74	-1,422	Algorithm converged.	-2,42	-0,42	0,32	Algorithm converged.	0,14	0,75	0,0054	0,675	3,12	Algorithm converged.	1,34	7,27
	65-74	100	8,4	2	2	108	9,1	9	8,3	0,22	Algorithm converged.	0,05	1,07	-6,333	Algorithm converged.	-12,22	-0,44	0,24	Algorithm converged.	0,05	1,08	0,0606		4,17	Algorithm converged.	0,92	18,82
	>=75	49	4,1	2	4,1	34	2,8	9	26,5	0,12	Algorithm converged.	0,02	0,59	-22,389	Algorithm converged.	-38,22	-6,56	0,15	Algorithm converged.	0,04	0,67	0,006		6,49	Algorithm converged.	1,49	28,16
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	2	0,8	0,46	Algorithm converged.	0,04	5,14	-0,442	Algorithm converged.	-1,81	0,92	0,47	Algorithm converged.	0,04	5,1	0,6112	0,1689	2,15	Algorithm converged.	0,2	23,55
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	1	0,6	183	15,3	4	2,2	0,29	Algorithm converged.	0,03	2,58	-1,553	Algorithm converged.	-4,01	0,9	0,29	Algorithm converged.	0,03	2,56	0,3781		3,45	Algorithm converged.	0,39	30,58
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	10	4,9	0	Algorithm converged.	NE	NE	-4,878	Algorithm converged.	-7,83	-1,93	NE	Algorithm not converged.	NE	NE	0,002		NE	Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,5	9	1,5	561	47	24	4,3	0,35	Algorithm converged.	0,16	0,75	-2,753	Algorithm converged.	-4,7	-0,81	0,36	Algorithm converged.	0,17	0,76	0,0052		2,8	Algorithm converged.	1,32	5,98
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Country	USA	1116	93,6	9	0,8	1112	93,2	34	3,1	0,26	Algorithm converged.	0,12	0,54	-2,251	Algorithm converged.	-3,39	-1,11	0,26	Algorithm converged.	0,13	0,55	0,0001	0,7405	3,79	Algorithm converged.	1,83	7,87
	MEX	76	6,4	2	2,6	81	6,8	6	7,4	0,34	Algorithm converged.	0,07	1,73	-4,776	Algorithm converged.	-11,52	1,97	0,36	Algorithm converged.	0,07	1,71	0,2783		2,81	Algorithm converged.	0,59	13,52
Baseline serostatus	Negative	798	66,9	7	0,9	813	68,1	28	3,4	0,25	Algorithm converged.	0,11	0,57	-2,567	Algorithm converged.	-3,98	-1,16	0,25	Algorithm converged.	0,11	0,58	0,0004	0,7944	3,93	Algorithm converged.	1,72	8,94
	Positive	311	26,1	2	0,6	284	23,8	9	3,2	0,2	Algorithm converged.	0,04	0,92	-2,526	Algorithm converged.	-4,75	-0,3	0,2	Algorithm converged.	0,04	0,93	0,0305		4,93	Algorithm converged.	1,07	22,61
	Other	83	7	2	2,4	96	8	3	3,1	0,77	Algorithm converged.	0,12	4,7	-0,715	Algorithm converged.	-5,51	4,08	0,77	Algorithm converged.	0,13	4,5	1		1,3	Algorithm converged.	0,22	7,58

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-1-eff-resp-tthos

POPULATION: mFAS

ENDPOINT: All-cause death by day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	1	0,1	1193	100	3	0,3	0,34	Algorithm converged.	0,03	3,25	-0,168	Algorithm converged.	-0,5	0,16	0,33	Algorithm converged.	0,03	3,2	0,6247		3	Algorithm converged.	0,31	28,78

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-2-eff-resp-dth29

POPULATION: mFAS
 ENDPOINT: All-cause death by day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	1	0,1	1193	100	3	0,3	0,33	Algorithm converged.	0,03	3,21	-0,168	Algorithm converged.	-0,5	0,16	0,33	Algorithm converged.	0,03	3,2	0,6247		3	Algorithm converged.	0,31	28,78
Sex	Male	579	48,6	1	0,2	580	48,6	1	0,2	1	Algorithm converged.	0,06	16,05	0	Algorithm converged.	-0,48	0,48	1	Algorithm converged.	0,06	15,98	1	0,1885	1	Algorithm converged.	0,06	15,92
	Female	613	51,4	0	0	613	51,4	2	0,3	0	Algorithm converged.	NE	NE	-0,326	Algorithm converged.	-0,78	0,13	NE	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
Age	18-64	1043	87,5	1	0,1	1051	88,1	1	0,1	1,01	Algorithm converged.	0,06	16,13	0,001	Algorithm converged.	-0,26	0,27	1,01	Algorithm converged.	0,06	16,09	1	0,3426	0,99	Algorithm converged.	0,06	15,84
	65-74	100	8,4	0	0	108	9,1	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	>=75	49	4,1	0	0	34	2,8	2	5,9	0	Algorithm converged.	NE	NE	-5,882	Algorithm converged.	-13,79	2,03	NE	Algorithm not converged.	NE	NE	0,1649		NE	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	0	0	NE	Algorithm not converged.	NE	NE	0,385	Algorithm converged.	-0,37	1,14	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	0	0	183	15,3	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	2	1	0	Algorithm converged.	NE	NE	-0,976	Algorithm converged.	-2,32	0,37	NE	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,5	0	0	561	47	1	0,2	0	Algorithm converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,17	NE	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Country	USA	1116	93,6	1	0,1	1112	93,2	2	0,2	0,5	Algorithm converged.	0,05	5,5	-0,09	Algorithm converged.	-0,39	0,21	0,5	Algorithm converged.	0,05	5,49	0,6242	0,4208	2,01	Algorithm converged.	0,18	22,1
	MEX	76	6,4	0	0	81	6,8	1	1,2	0	Algorithm converged.	NE	NE	-1,235	Algorithm converged.	-3,64	1,17	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Baseline serostatus	Negative	798	66,9	0	0	813	68,1	3	0,4	0	Algorithm converged.	NE	NE	-0,369	Algorithm converged.	-0,79	0,05	NE	Algorithm not converged.	NE	NE	0,2496	0,0372	NE	Algorithm not converged.	NE	NE
	Positive	311	26,1	1	0,3	284	23,8	0	0	NE	Algorithm not converged.	NE	NE	0,322	Algorithm converged.	-0,31	0,95	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Other	83	7	0	0	96	8	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-2-eff-resp-dth29

POPULATION: mFAS

ENDPOINT: All-cause death by day 169

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	1	0,1	1193	100	7	0,6	0,14	Algorithm converged.	0,02	1,17	-0,503	Algorithm converged.	-0,97	-0,04	0,14	Algorithm converged.	0,02	1,16	0,0699		6,99	Algorithm converged.	0,86	56,76

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-3-eff-resp-dth169

POPULATION: mFAS
 ENDPOINT: All-cause death by day 169
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	1	0,1	1193	100	7	0,6	0,14	Algorithm converged.	0,02	1,16	-0,503	Algorithm converged.	-0,97	-0,04	0,14	Algorithm converged.	0,02	1,16	0,0699		6,99	Algorithm converged.	0,86	56,76
Sex	Male	579	48,6	1	0,2	580	48,6	2	0,3	0,5	Algorithm converged.	0,05	5,53	-0,172	Algorithm converged.	-0,76	0,41	0,5	Algorithm converged.	0,05	5,51	1	0,1368	2	Algorithm converged.	0,18	21,96
	Female	613	51,4	0	0	613	51,4	5	0,8	0	Algorithm converged.	NE	NE	-0,816	Algorithm converged.	-1,53	-0,1	NE	* Algorithm not converged.	NE	NE	0,062		NE	* Algorithm not converged.	NE	NE
Age	18-64	1043	87,5	1	0,1	1051	88,1	1	0,1	1,01	Algorithm converged.	0,06	16,13	0,001	Algorithm converged.	-0,26	0,27	1,01	Algorithm converged.	0,06	16,09	1	0,1524	0,99	Algorithm converged.	0,06	15,84
	65-74	100	8,4	0	0	108	9,1	1	0,9	0	Algorithm converged.	NE	NE	-0,926	Algorithm converged.	-2,73	0,88	NE	* Algorithm not converged.	NE	NE	1		NE	* Algorithm not converged.	NE	NE
	>=75	49	4,1	0	0	34	2,8	5	14,7	0	Algorithm converged.	NE	NE	-14,706	Algorithm converged.	-26,61	-2,8	NE	* Algorithm not converged.	NE	NE	0,0096		NE	* Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	0	0	NE	* Algorithm not converged.	NE	NE	0,385	Algorithm converged.	-0,37	1,14	NE	* Algorithm not converged.	NE	NE	1		NE	* Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	0	0	183	15,3	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	2	1	0	Algorithm converged.	NE	NE	-0,976	Algorithm converged.	-2,32	0,37	NE	* Algorithm not converged.	NE	NE	0,5003		NE	* Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,5	0	0	561	47	5	0,9	0	Algorithm converged.	NE	NE	-0,891	Algorithm converged.	-1,67	-0,11	NE	* Algorithm not converged.	NE	NE	0,0273		NE	* Algorithm not converged.	NE	NE
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE
Country	USA	1116	93,6	1	0,1	1112	93,2	5	0,4	0,2	Algorithm converged.	0,02	1,7	-0,36	Algorithm converged.	-0,79	0,07	0,2	Algorithm converged.	0,02	1,7	0,1239	0,4423	5,02	Algorithm converged.	0,59	42,88
	MEX	76	6,4	0	0	81	6,8	2	2,5	0	Algorithm converged.	NE	NE	-2,469	Algorithm converged.	-5,85	0,91	NE	* Algorithm not converged.	NE	NE	0,4973		NE	* Algorithm not converged.	NE	NE
Baseline serostatus	Negative	798	66,9	0	0	813	68,1	6	0,7	0	Algorithm converged.	NE	NE	-0,738	Algorithm converged.	-1,33	-0,15	NE	* Algorithm not converged.	NE	NE	0,031	0,0184	NE	* Algorithm not converged.	NE	NE
	Positive	311	26,1	1	0,3	284	23,8	0	0	NE	* Algorithm not converged.	NE	NE	0,322	Algorithm converged.	-0,31	0,95	NE	* Algorithm not converged.	NE	NE	1		NE	* Algorithm not converged.	NE	NE
	Other	83	7	0	0	96	8	1	1	0	Algorithm converged.	NE	NE	-1,042	Algorithm converged.	-3,07	0,99	NE	* Algorithm not converged.	NE	NE	1		NE	* Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-3-eff-resp-dth169

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related hospitalization or all-cause death from day 4 through day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1189	99,7	8	0,7	1193	100	29	2,4	0,27	Algorithm converged.	0,12	0,6	-1,758	Algorithm converged.	-2,75	-0,77	0,28	Algorithm converged.	0,13	0,6	0,0005		3,61	Algorithm converged.	1,66	7,87

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-4-eff-resp-tthos2

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related hospitalization or all-cause death from day 4 through day 29

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1189	99,7	8	0,7	1193	100	29	2,4	0,27	Algorithm converged.	0,12	0,6	-1,758	Algorithm converged.	-2,75	-0,77	0,28	Algorithm converged.	0,13	0,6	0,0005		3,61	Algorithm converged.	1,66	7,87
Sex	Male	577	48,5	7	1,2	580	48,6	13	2,2	0,54	Algorithm converged.	0,21	1,35	-1,028	Algorithm converged.	-2,53	0,47	0,54	Algorithm converged.	0,22	1,35	0,1799	0,0226	1,85	Algorithm converged.	0,74	4,6
	Female	612	51,5	1	0,2	613	51,4	16	2,6	0,06	Algorithm converged.	0,01	0,46	-2,447	Algorithm converged.	-3,75	-1,14	0,06	Algorithm converged.	0,01	0,47	0,0003		15,97	Algorithm converged.	2,13	120,08
Age	18-64	1040	87,5	6	0,6	1051	88,1	16	1,5	0,38	Algorithm converged.	0,15	0,96	-0,945	Algorithm converged.	-1,82	-0,07	0,38	Algorithm converged.	0,15	0,96	0,0342	0,3436	2,64	Algorithm converged.	1,04	6,72
	65-74	100	8,4	1	1	108	9,1	5	4,6	0,21	Algorithm converged.	0,02	1,81	-3,63	Algorithm converged.	-8,05	0,79	0,22	Algorithm converged.	0,03	1,82	0,214		4,63	Algorithm converged.	0,55	38,95
	>=75	49	4,1	1	2	34	2,8	8	23,5	0,07	Algorithm converged.	0,01	0,57	-21,489	Algorithm converged.	-36,29	-6,69	0,09	Algorithm converged.	0,01	0,66	0,0029		11,53	Algorithm converged.	1,51	87,99
Baseline viral load categories	<=10^5 copies/mL	260	21,9	1	0,4	242	20,3	0	0	NE *	Algorithm not converged.	NE	NE	0,385	Algorithm converged.	-0,37	1,14	NE *	Algorithm not converged.	NE	NE	1	0,1152	NE *	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	157	13,2	1	0,6	183	15,3	2	1,1	0,58	Algorithm converged.	0,05	6,46	-0,456	Algorithm converged.	-2,41	1,5	0,58	Algorithm converged.	0,05	6,37	1		1,72	Algorithm converged.	0,16	18,74
	>10^6 copies/mL - <=10^7 copies/mL	181	15,2	0	0	205	17,2	6	2,9	0	Algorithm converged.	NE	NE	-2,927	Algorithm converged.	-5,23	-0,62	NE *	Algorithm not converged.	NE	NE	0,0318		NE *	Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,6	6	1	561	47	21	3,7	0,26	Algorithm converged.	0,11	0,66	-2,726	Algorithm converged.	-4,49	-0,96	0,27	Algorithm converged.	0,11	0,67	0,0023		3,68	Algorithm converged.	1,5	9,05
	Unknown	1	0,1	0	0	2	0,2	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1113	93,6	6	0,5	1112	93,2	26	2,3	0,23	Algorithm converged.	0,09	0,55	-1,799	Algorithm converged.	-2,79	-0,81	0,23	Algorithm converged.	0,1	0,56	0,0004	0,2801	4,34	Algorithm converged.	1,79	10,5
	MEX	76	6,4	2	2,6	81	6,8	3	3,7	0,7	Algorithm converged.	0,11	4,33	-1,072	Algorithm converged.	-6,54	4,39	0,71	Algorithm converged.	0,12	4,14	1		1,41	Algorithm converged.	0,24	8,19
Baseline serostatus	Negative	796	66,9	5	0,6	813	68,1	24	3	0,21	Algorithm converged.	0,08	0,55	-2,324	Algorithm converged.	-3,61	-1,04	0,21	Algorithm converged.	0,08	0,55	0,0005	0,3208	4,7	Algorithm converged.	1,8	12,26
	Positive	311	26,2	2	0,6	284	23,8	3	1,1	0,61	Algorithm converged.	0,1	3,65	-0,413	Algorithm converged.	-1,9	1,07	0,61	Algorithm converged.	0,1	3,62	0,6735		1,64	Algorithm converged.	0,28	9,76
	Other	82	6,9	1	1,2	96	8	2	2,1	0,58	Algorithm converged.	0,05	6,52	-0,864	Algorithm converged.	-4,58	2,85	0,59	Algorithm converged.	0,05	6,34	1		1,71	Algorithm converged.	0,16	18,5

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-4-eff-resp-tthos2

POPULATION: mFAS

ENDPOINT: Proportion of patients with ≥ 1 COVID-19-related hospitalization, emergency room (ER) visit, or all-cause death through day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test			Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	13	1,1	1193	100	53	4,4	0,24	Algorithm converged.	0,13	0,44	-3,352	Algorithm converged.	-4,66	-2,04	0,25	Algorithm converged.	0,13	0,45	<0.0001		4,07	Algorithm converged.	2,23	7,43

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If $n_p < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-5-eff-resp-tthcvd

POPULATION: mFAS
 ENDPOINT: Proportion of patients with ≥ 1 COVID-19-related hospitalization, emergency room (ER) visit, or all-cause death through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	13	1.1	1193	100	53	4.4	0.24	Algorithm converged.	0.13	0.44	-3.352	Algorithm converged.	-4.66	-2.04	0.25	Algorithm converged.	0.13	0.45	<0.0001		4.07	Algorithm converged.	2.23	7.43
Sex	Male	579	48.6	11	1.9	580	48.6	27	4.7	0.4	Algorithm converged.	0.19	0.81	-2.755	Algorithm converged.	-4.8	-0.71	0.41	Algorithm converged.	0.2	0.81	0.0085	0.0195	2.45	Algorithm converged.	1.23	4.89
	Female	613	51.4	2	0.3	613	51.4	26	4.2	0.07	Algorithm converged.	0.02	0.31	-3.915	Algorithm converged.	-5.57	-2.26	0.08	Algorithm converged.	0.02	0.32	<0.0001		13	Algorithm converged.	3.1	54.53
Age	18-64	1043	87.5	8	0.8	1051	88.1	31	2.9	0.25	Algorithm converged.	0.12	0.56	-2.183	Algorithm converged.	-3.33	-1.03	0.26	Algorithm converged.	0.12	0.56	0.0002	0.5998	3.85	Algorithm converged.	1.78	8.33
	65-74	100	8.4	3	3	108	9.1	11	10.2	0.27	Algorithm converged.	0.07	1.01	-7.185	Algorithm converged.	-13.8	-0.57	0.29	Algorithm converged.	0.08	1.03	0.0517		3.4	Algorithm converged.	0.98	11.82
	≥ 75	49	4.1	2	4.1	34	2.8	11	32.4	0.09	Algorithm converged.	0.02	0.44	-28.271	Algorithm converged.	-44.94	-11.6	0.13	Algorithm converged.	0.03	0.53	0.0012		7.93	Algorithm converged.	1.87	33.51
Baseline viral load categories	$\leq 10^5$ copies/mL	260	21.8	1	0.4	242	20.3	6	2.5	0.15	Algorithm converged.	0.02	1.27	-2.095	Algorithm converged.	-4.19	0	0.16	Algorithm converged.	0.02	1.28	0.06	0.606	6.45	Algorithm converged.	0.78	53.16
	$>10^5$ copies/mL - $\leq 10^6$ copies/mL	158	13.3	1	0.6	183	15.3	5	2.7	0.23	Algorithm converged.	0.03	1.96	-2.099	Algorithm converged.	-4.77	0.57	0.23	Algorithm converged.	0.03	1.96	0.2222		4.32	Algorithm converged.	0.51	36.56
	$>10^6$ copies/mL - $\leq 10^7$ copies/mL	183	15.4	1	0.5	205	17.2	12	5.9	0.09	Algorithm converged.	0.01	0.69	-5.307	Algorithm converged.	-8.69	-1.92	0.09	Algorithm converged.	0.01	0.71	0.0035		10.71	Algorithm converged.	1.41	81.58
	$>10^7$ copies/mL	590	49.5	10	1.7	561	47	30	5.3	0.31	Algorithm converged.	0.15	0.63	-3.653	Algorithm converged.	-5.79	-1.52	0.32	Algorithm converged.	0.16	0.64	0.0007		3.16	Algorithm converged.	1.56	6.39
	Unknown	1	0.1	0	0	2	0.2	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1116	93.6	11	1	1112	93.2	47	4.2	0.23	Algorithm converged.	0.12	0.44	-3.241	Algorithm converged.	-4.56	-1.92	0.23	Algorithm converged.	0.12	0.45	<0.0001	0.637	4.29	Algorithm converged.	2.24	8.22
	MEX	76	6.4	2	2.6	81	6.8	6	7.4	0.34	Algorithm converged.	0.07	1.73	-4.776	Algorithm converged.	-11.52	1.97	0.36	Algorithm converged.	0.07	1.71	0.2783		2.81	Algorithm converged.	0.59	13.52
Baseline serostatus	Negative	798	66.9	8	1	813	68.1	37	4.6	0.21	Algorithm converged.	0.1	0.46	-3.549	Algorithm converged.	-5.14	-1.96	0.22	Algorithm converged.	0.1	0.47	<0.0001	0.9524	4.54	Algorithm converged.	2.13	9.69
	Positive	311	26.1	3	1	284	23.8	13	4.6	0.2	Algorithm converged.	0.06	0.72	-3.613	Algorithm converged.	-6.28	-0.95	0.21	Algorithm converged.	0.06	0.73	0.0092		4.75	Algorithm converged.	1.37	16.48
	Other	83	7	2	2.4	96	8	3	3.1	0.77	Algorithm converged.	0.12	4.7	-0.715	Algorithm converged.	-5.51	4.08	0.77	Algorithm converged.	0.13	4.5	1		1.3	Algorithm converged.	0.22	7.58

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-5-eff-resp-thcvd

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related hospitalization through day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk					Relative Risk								
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	11	0,9	1193	100	40	3,4	0,27	Algorithm converged.	0,14	0,53	-2,43	Algorithm converged.	-3,59	-1,27	0,28	Algorithm converged.	0,14	0,53	<0.0001		3,63	Algorithm converged.	1,87	7,05

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-6-eff-resp-hosp

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related hospitalization through day 29

MODEL: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Interaction Test			Relative Risk			
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	11	0,9	1193	100	40	3,4	0,27	Algorithm converged.	0,14	0,53	-2,43	Algorithm converged.	-3,59	-1,27	0,28	Algorithm converged.	0,14	0,53	<0,0001		3,63	Algorithm converged.	1,87	7,05
Sex	Male	579	48,6	9	1,6	580	48,6	20	3,4	0,44	Algorithm converged.	0,2	0,98	-1,894	Algorithm converged.	-3,69	-0,1	0,45	Algorithm converged.	0,21	0,98	0,0391	0,0478	2,22	Algorithm converged.	1,02	4,83
	Female	613	51,4	2	0,3	613	51,4	20	3,3	0,1	Algorithm converged.	0,02	0,42	-2,936	Algorithm converged.	-4,41	-1,46	0,1	Algorithm converged.	0,02	0,43	0,0001		10	Algorithm converged.	2,35	42,6
Age	18-64	1043	87,5	7	0,7	1051	88,1	22	2,1	0,32	Algorithm converged.	0,13	0,74	-1,422	Algorithm converged.	-2,42	-0,42	0,32	Algorithm converged.	0,14	0,75	0,0054	0,675	3,12	Algorithm converged.	1,34	7,27
	65-74	100	8,4	2	2	108	9,1	9	8,3	0,22	Algorithm converged.	0,05	1,07	-6,333	Algorithm converged.	-12,22	-0,44	0,24	Algorithm converged.	0,05	1,08	0,0606		4,17	Algorithm converged.	0,92	18,82
	>=75	49	4,1	2	4,1	34	2,8	9	26,5	0,12	Algorithm converged.	0,02	0,59	-22,389	Algorithm converged.	-38,22	-6,56	0,15	Algorithm converged.	0,04	0,67	0,006		6,49	Algorithm converged.	1,49	28,16
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	2	0,8	0,46	Algorithm converged.	0,04	5,14	-0,442	Algorithm converged.	-1,81	0,92	0,47	Algorithm converged.	0,04	5,1	0,6112	0,1689	2,15	Algorithm converged.	0,2	23,55
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	1	0,6	183	15,3	4	2,2	0,29	Algorithm converged.	0,03	2,58	-1,553	Algorithm converged.	-4,01	0,9	0,29	Algorithm converged.	0,03	2,56	0,3781		3,45	Algorithm converged.	0,39	30,58
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	10	4,9	0	Algorithm converged.	NE	NE	-4,878	Algorithm converged.	-7,83	-1,93	NE	Algorithm not converged.	NE	NE	0,002		NE	Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,5	9	1,5	561	47	24	4,3	0,35	Algorithm converged.	0,16	0,75	-2,753	Algorithm converged.	-4,7	-0,81	0,36	Algorithm converged.	0,17	0,76	0,0052		2,8	Algorithm converged.	1,32	5,98
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Country	USA	1116	93,6	9	0,8	1112	93,2	34	3,1	0,26	Algorithm converged.	0,12	0,54	-2,251	Algorithm converged.	-3,39	-1,11	0,26	Algorithm converged.	0,13	0,55	0,0001	0,7405	3,79	Algorithm converged.	1,83	7,87
	MEX	76	6,4	2	2,6	81	6,8	6	7,4	0,34	Algorithm converged.	0,07	1,73	-4,776	Algorithm converged.	-11,52	1,97	0,36	Algorithm converged.	0,07	1,71	0,2783		2,81	Algorithm converged.	0,59	13,52
Baseline serostatus	Negative	798	66,9	7	0,9	813	68,1	28	3,4	0,25	Algorithm converged.	0,11	0,57	-2,567	Algorithm converged.	-3,98	-1,16	0,25	Algorithm converged.	0,11	0,58	0,0004	0,7944	3,93	Algorithm converged.	1,72	8,94
	Positive	311	26,1	2	0,6	284	23,8	9	3,2	0,2	Algorithm converged.	0,04	0,92	-2,526	Algorithm converged.	-4,75	-0,3	0,2	Algorithm converged.	0,04	0,93	0,0305		4,93	Algorithm converged.	1,07	22,61
	Other	83	7	2	2,4	96	8	3	3,1	0,77	Algorithm converged.	0,12	4,7	-0,715	Algorithm converged.	-5,51	4,08	0,77	Algorithm converged.	0,13	4,5	1		1,3	Algorithm converged.	0,22	7,58

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-6-eff-resp-hosp

POPULATION: mFAS

ENDPOINT: Proportion of patients with >=1 COVID-19-related ER visit through day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	3	0,3	1193	100	16	1,3	0,18	Algorithm converged.	0,05	0,64	-1,089	Algorithm converged.	-1,8	-0,38	0,19	Algorithm converged.	0,05	0,64	0,0043		5,33	Algorithm converged.	1,56	18,24

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-7-eff-resp-er

POPULATION: mFAS
 ENDPOINT: Proportion of patients with >=1 COVID-19-related ER visit through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk		Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	1192	100	3	0,3	1193	100	16	1,3	0,19	Algorithm converged.	0,05	0,64	-1,089	Algorithm converged.	-1,8	-0,38	0,19	Algorithm converged.	0,05	0,64	0,0043		5,33	Algorithm converged.	1,56	18,24	
Sex	Male	579	48,6	3	0,5	580	48,6	9	1,6	0,33	Algorithm converged.	0,09	1,23	-1,034	Algorithm converged.	-2,2	0,13	0,33	Algorithm converged.	0,09	1,23	0,1439	0,0788	2,99	Algorithm converged.	0,81	11,01	
	Female	613	51,4	0	0	613	51,4	7	1,1	0	Algorithm converged.	NE	NE	-1,142	Algorithm converged.	-1,98	-0,3	NE	Algorithm not converged.	NE	NE	0,0154		NE	*	Algorithm not converged.	NE	NE
Age	18-64	1043	87,5	2	0,2	1051	88,1	10	1	0,2	Algorithm converged.	0,04	0,92	-0,76	Algorithm converged.	-1,4	-0,12	0,2	Algorithm converged.	0,04	0,92	0,0381	0,5846	4,96	Algorithm converged.	1,09	22,59	
	65-74	100	8,4	1	1	108	9,1	4	3,7	0,26	Algorithm converged.	0,03	2,39	-2,704	Algorithm converged.	-6,76	1,36	0,27	Algorithm converged.	0,03	2,38	0,3708		3,7	Algorithm converged.	0,42	32,58	
	>=75	49	4,1	0	0	34	2,8	2	5,9	0	Algorithm converged.	NE	NE	-5,882	Algorithm converged.	-13,79	2,03	NE	Algorithm not converged.	NE	NE	0,1649		NE	*	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	260	21,8	0	0	242	20,3	4	1,7	0	Algorithm converged.	NE	NE	-1,653	Algorithm converged.	-3,26	-0,05	NE	Algorithm not converged.	NE	NE	0,0533	0,4159	NE	*	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	0	0	183	15,3	2	1,1	0	Algorithm converged.	NE	NE	-1,093	Algorithm converged.	-2,6	0,41	NE	Algorithm not converged.	NE	NE	0,5012		NE	*	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	1	0,5	205	17,2	2	1	0,56	Algorithm converged.	0,05	6,2	-0,429	Algorithm converged.	-2,15	1,29	0,56	Algorithm converged.	0,05	6,13	1		1,79	Algorithm converged.	0,16	19,53	
	>10^7 copies/mL	590	49,5	2	0,3	561	47	8	1,4	0,24	Algorithm converged.	0,05	1,11	-1,087	Algorithm converged.	-2,17	0	0,24	Algorithm converged.	0,05	1,11	0,0585		4,21	Algorithm converged.	0,9	19,72	
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE
Country	USA	1116	93,6	3	0,3	1112	93,2	16	1,4	0,18	Algorithm converged.	0,05	0,64	-1,17	Algorithm converged.	-1,93	-0,41	0,19	Algorithm converged.	0,05	0,64	0,0024	1	5,35	Algorithm converged.	1,56	18,32	
	MEX	76	6,4	0	0	81	6,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE
Baseline serostatus	Negative	798	66,9	2	0,3	813	68,1	10	1,2	0,2	Algorithm converged.	0,04	0,92	-0,979	Algorithm converged.	-1,81	-0,15	0,2	Algorithm converged.	0,04	0,93	0,038	0,824	4,91	Algorithm converged.	1,08	22,33	
	Positive	311	26,1	1	0,3	284	23,8	6	2,1	0,15	Algorithm converged.	0,02	1,25	-1,791	Algorithm converged.	-3,58	0	0,15	Algorithm converged.	0,02	1,26	0,0583		6,57	Algorithm converged.	0,8	54,24	
	Other	83	7	0	0	96	8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-7-eff-resp-er

POPULATION: mFAS

ENDPOINT: Proportion of patients requiring mechanical ventilation due to COVID-19 by day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	1	0,1	1193	100	5	0,4	0,2	Algorithm converged.	0,02	1,75	-0,335	Algorithm converged.	-0,74	0,07	0,2	Algorithm converged.	0,02	1,71	0,2182		5	Algorithm converged.	0,58	42,7

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-8-eff-resp-mecvent

POPULATION: mFAS
 ENDPOINT: Proportion of patients requiring mechanical ventilation due to COVID-19 by day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	1	0,1	1193	100	5	0,4	0,2	Algorithm converged.	0,02	1,71	-0,335	Algorithm converged.	-0,74	0,07	0,2	Algorithm converged.	0,02	1,71	0,2182		5	Algorithm converged.	0,58	42,7
Sex	Male	579	48,6	1	0,2	580	48,6	1	0,2	1	Algorithm converged.	0,06	16,05	0	Algorithm converged.	-0,48	0,48	1	Algorithm converged.	0,06	15,98	1	0,1042	1	Algorithm converged.	0,06	15,92
	Female	613	51,4	0	0	613	51,4	4	0,7	0	Algorithm converged.	NE	NE	-0,653	Algorithm converged.	-1,29	-0,02	NE	* Algorithm not converged.	NE	NE	0,1244		NE	* Algorithm not converged.	NE	NE
Age	18-64	1043	87,5	1	0,1	1051	88,1	1	0,1	1,01	Algorithm converged.	0,06	16,13	0,001	Algorithm converged.	-0,26	0,27	1,01	Algorithm converged.	0,06	16,09	1		0,99	Algorithm converged.	0,06	15,84
	65-74	100	8,4	0	0	108	9,1	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE
	>=75	49	4,1	0	0	34	2,8	4	11,8	0	Algorithm converged.	NE	NE	-11,765	Algorithm converged.	-22,59	-0,93	NE	* Algorithm not converged.	NE	NE	0,0252		NE	* Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	0	0	NE	* Algorithm not converged.	NE	NE	0,385	Algorithm converged.	-0,37	1,14	NE	* Algorithm not converged.	NE	NE	1		NE	* Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	0	0	183	15,3	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	1	0,5	0	Algorithm converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,47	NE	* Algorithm not converged.	NE	NE	1		NE	* Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,5	0	0	561	47	4	0,7	0	Algorithm converged.	NE	NE	-0,713	Algorithm converged.	-1,41	-0,02	NE	* Algorithm not converged.	NE	NE	0,0561		NE	* Algorithm not converged.	NE	NE
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE
Country	USA	1116	93,6	1	0,1	1112	93,2	2	0,2	0,5	Algorithm converged.	0,05	5,5	-0,09	Algorithm converged.	-0,39	0,21	0,5	Algorithm converged.	0,05	5,49	0,6242	0,2164	2,01	Algorithm converged.	0,18	22,1
	MEX	76	6,4	0	0	81	6,8	3	3,7	0	Algorithm converged.	NE	NE	-3,704	Algorithm converged.	-7,82	0,41	NE	* Algorithm not converged.	NE	NE	0,246		NE	* Algorithm not converged.	NE	NE
Baseline serostatus	Negative	798	66,9	0	0	813	68,1	3	0,4	0	Algorithm converged.	NE	NE	-0,369	Algorithm converged.	-0,79	0,05	NE	* Algorithm not converged.	NE	NE	0,2496	0,2233	NE	* Algorithm not converged.	NE	NE
	Positive	311	26,1	1	0,3	284	23,8	2	0,7	0,45	Algorithm converged.	0,04	5,04	-0,383	Algorithm converged.	-1,54	0,78	0,46	Algorithm converged.	0,04	5,01	0,6081		2,19	Algorithm converged.	0,2	24,02
	Other	83	7	0	0	96	8	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	* Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-8-eff-resp-mecvent

POPULATION: mFAS

ENDPOINT: Proportion of patients requiring supplemental oxygen due to COVID-19 by day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	8	0,7	1193	100	31	2,6	0,25	Algorithm converged.	0,12	0,56	-1,927	Algorithm converged.	-2,94	-0,91	0,26	Algorithm converged.	0,12	0,56	0,0002		3,87	Algorithm converged.	1,79	8,39

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-9-eff-resp-oxysup

POPULATION: mFAS
 ENDPOINT: Proportion of patients requiring supplemental oxygen due to COVID-19 by day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	8	0,7	1193	100	31	2,6	0,25	Algorithm converged.	0,12	0,55	-1,927	Algorithm converged.	-2,94	-0,91	0,26	Algorithm converged.	0,12	0,56	0,0002		3,87	Algorithm converged.	1,79	8,39
Sex	Male	579	48,6	6	1	580	48,6	15	2,6	0,39	Algorithm converged.	0,15	1,02	-1,55	Algorithm converged.	-3,08	-0,02	0,4	Algorithm converged.	0,16	1,03	0,048	0,1659	2,5	Algorithm converged.	0,98	6,39
	Female	613	51,4	2	0,3	613	51,4	16	2,6	0,12	Algorithm converged.	0,03	0,53	-2,284	Algorithm converged.	-3,62	-0,94	0,13	Algorithm converged.	0,03	0,54	0,0012		8	Algorithm converged.	1,85	34,64
Age	18-64	1043	87,5	5	0,5	1051	88,1	18	1,7	0,28	Algorithm converged.	0,1	0,75	-1,233	Algorithm converged.	-2,12	-0,34	0,28	Algorithm converged.	0,1	0,75	0,0102	0,7863	3,57	Algorithm converged.	1,33	9,59
	65-74	100	8,4	1	1	108	9,1	4	3,7	0,26	Algorithm converged.	0,03	2,39	-2,704	Algorithm converged.	-6,76	1,36	0,27	Algorithm converged.	0,03	2,38	0,3708		3,7	Algorithm converged.	0,42	32,58
	>=75	49	4,1	2	4,1	34	2,8	9	26,5	0,12	Algorithm converged.	0,02	0,59	-22,389	Algorithm converged.	-38,22	-6,56	0,15	Algorithm converged.	0,04	0,67	0,006		6,49	Algorithm converged.	1,49	28,16
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	2	0,8	0,46	Algorithm converged.	0,04	5,14	-0,442	Algorithm converged.	-1,81	0,92	0,47	Algorithm converged.	0,04	5,1	0,6112	0,3112	2,15	Algorithm converged.	0,2	23,55
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	1	0,6	183	15,3	2	1,1	0,58	Algorithm converged.	0,05	6,42	-0,46	Algorithm converged.	-2,41	1,49	0,58	Algorithm converged.	0,05	6,33	1		1,73	Algorithm converged.	0,16	18,86
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	7	3,4	0	Algorithm converged.	NE	NE	-3,415	Algorithm converged.	-5,9	-0,93	NE	Algorithm not converged.	NE	NE	0,0158		NE	Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	49,5	6	1	561	47	20	3,6	0,28	Algorithm converged.	0,11	0,7	-2,548	Algorithm converged.	-4,28	-0,81	0,29	Algorithm converged.	0,12	0,71	0,0037		3,51	Algorithm converged.	1,42	8,67
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Country	USA	1116	93,6	6	0,5	1112	93,2	26	2,3	0,23	Algorithm converged.	0,09	0,55	-1,8	Algorithm converged.	-2,79	-0,81	0,23	Algorithm converged.	0,1	0,56	0,0004	0,522	4,35	Algorithm converged.	1,8	10,52
	MEX	76	6,4	2	2,6	81	6,8	5	6,2	0,41	Algorithm converged.	0,08	2,18	-3,541	Algorithm converged.	-9,9	2,82	0,43	Algorithm converged.	0,09	2,13	0,4441		2,35	Algorithm converged.	0,47	11,73
Baseline serostatus	Negative	798	66,9	4	0,5	813	68,1	21	2,6	0,19	Algorithm converged.	0,06	0,56	-2,082	Algorithm converged.	-3,28	-0,89	0,19	Algorithm converged.	0,07	0,56	0,0008	0,7615	5,15	Algorithm converged.	1,78	14,95
	Positive	311	26,1	2	0,6	284	23,8	7	2,5	0,26	Algorithm converged.	0,05	1,24	-1,822	Algorithm converged.	-3,83	0,19	0,26	Algorithm converged.	0,05	1,25	0,094		3,83	Algorithm converged.	0,8	18,3
	Other	83	7	2	2,4	96	8	3	3,1	0,77	Algorithm converged.	0,12	4,7	-0,715	Algorithm converged.	-5,51	4,08	0,77	Algorithm converged.	0,13	4,5	1		1,3	Algorithm converged.	0,22	7,58

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-9-eff-resp-oxysup

POPULATION: mFAS

ENDPOINT: Proportion of patients admitted to an ICU due to COVID-19 by day 29

MODEL: Stratified analysis for overall; stratification factor = country

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (efficacy)

		Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1192	100	3	0,3	1193	100	9	0,8	0,33	Algorithm converged.	0,09	1,24	-0,503	Algorithm converged.	-1,07	0,06	0,33	Algorithm converged.	0,09	1,23	0,145		3	Algorithm converged.	0,81	11,04

Test for interaction based on RR (Log-binomial regression).

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas

Output: t12-10-eff-resp-icu

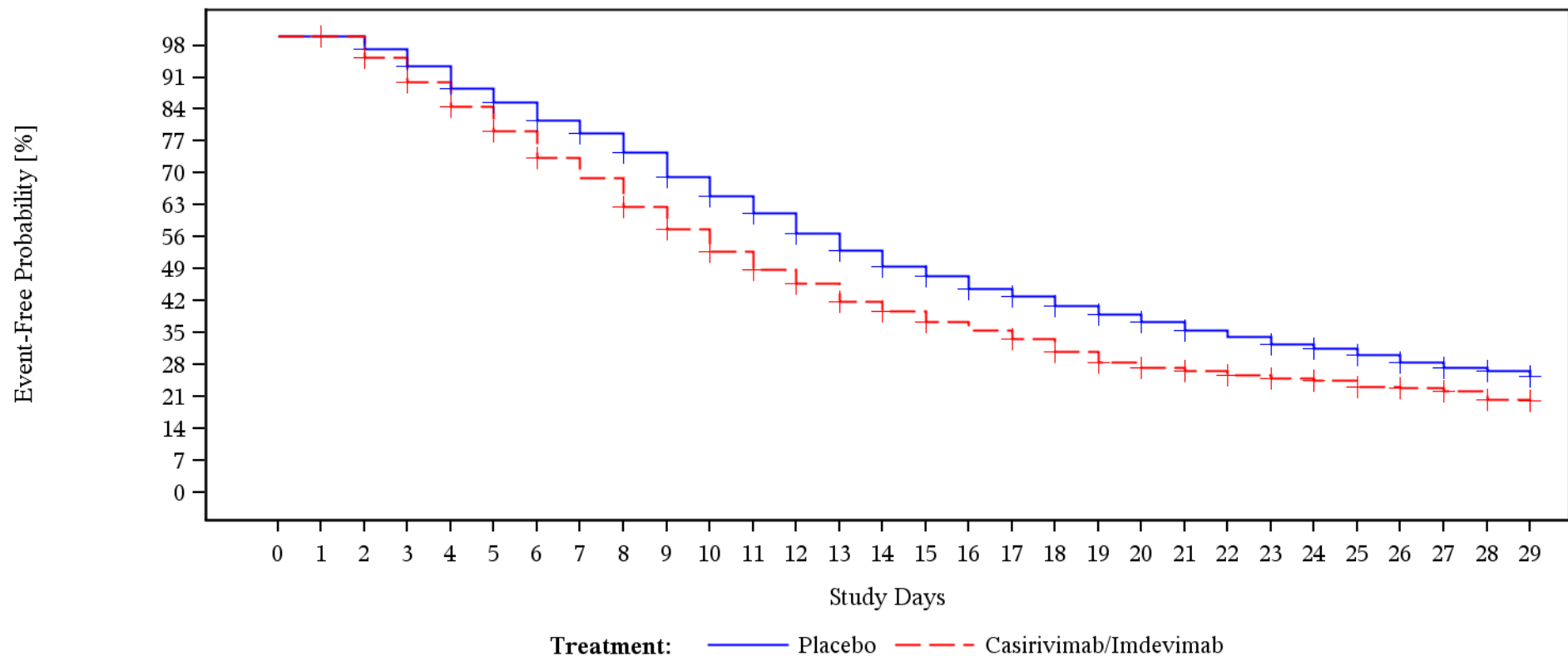
POPULATION: mFAS
 ENDPOINT: Proportion of patients admitted to an ICU due to COVID-19 by day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (efficacy)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk		Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1192	100	3	0,3	1193	100	9	0,8	0,33	Algorithm converged.	0,09	1,23	-0,503	Algorithm converged.	-1,07	0,06	0,33	Algorithm converged.	0,09	1,23	0,145		3	Algorithm converged.	0,81	11,04			
Sex	Male	579	48,6	2	0,3	580	48,6	3	0,5	0,67	Algorithm converged.	0,11	4	-0,172	Algorithm converged.	-0,93	0,58	0,67	Algorithm converged.	0,11	3,98	1	0,31	1,5	Algorithm converged.	0,25	8,93			
	Female	613	51,4	1	0,2	613	51,4	6	1	0,17	Algorithm converged.	0,02	1,38	-0,816	Algorithm converged.	-1,66	0,03	0,17	Algorithm converged.	0,02	1,38	0,1239		6	Algorithm converged.	0,72	49,69			
Age	18-64	1043	87,5	3	0,3	1051	88,1	2	0,2	1,51	Algorithm converged.	0,25	9,07	0,097	Algorithm converged.	-0,32	0,52	1,51	Algorithm converged.	0,25	9,03	0,686	0,0257	0,66	Algorithm converged.	0,11	3,95			
	65-74	100	8,4	0	0	108	9,1	4	3,7	0	Algorithm converged.	NE	NE	-3,704	Algorithm converged.	-7,27	-0,14	NE	*	Algorithm not converged.	NE	NE	0,1225		NE	*	Algorithm not converged.	NE	NE	
	>=75	49	4,1	0	0	34	2,8	3	8,8	0	Algorithm converged.	NE	NE	-8,824	Algorithm converged.	-18,36	0,71	NE	*	Algorithm not converged.	NE	NE	0,0651		NE	*	Algorithm not converged.	NE	NE	
Baseline viral load categories	<=10^5 copies/mL	260	21,8	1	0,4	242	20,3	0	0	NE	*	Algorithm not converged.	NE	NE	0,385	Algorithm converged.	-0,37	1,14	NE	*	Algorithm not converged.	NE	NE	1	0,2397	NE	*	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	158	13,3	0	0	183	15,3	2	1,1	0	Algorithm converged.	NE	NE	-1,093	Algorithm converged.	-2,6	0,41	NE	*	Algorithm not converged.	NE	NE	0,5012		NE	*	Algorithm not converged.	NE	NE	
	>10^6 copies/mL - <=10^7 copies/mL	183	15,4	0	0	205	17,2	1	0,5	0	Algorithm converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,47	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
	>10^7 copies/mL	590	49,5	2	0,3	561	47	6	1,1	0,31	Algorithm converged.	0,06	1,57	-0,731	Algorithm converged.	-1,7	0,24	0,32	Algorithm converged.	0,06	1,56	0,1683		3,16	Algorithm converged.	0,64	15,57			
	Unknown	1	0,1	0	0	2	0,2	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	
Country	USA	1116	93,6	3	0,3	1112	93,2	7	0,6	0,43	Algorithm converged.	0,11	1,65	-0,361	Algorithm converged.	-0,92	0,19	0,43	Algorithm converged.	0,11	1,65	0,2248	0,2695	2,34	Algorithm converged.	0,61	9,03			
	MEX	76	6,4	0	0	81	6,8	2	2,5	0	Algorithm converged.	NE	NE	-2,469	Algorithm converged.	-5,85	0,91	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	*	Algorithm not converged.	NE	NE	
Baseline serostatus	Negative	798	66,9	1	0,1	813	68,1	4	0,5	0,25	Algorithm converged.	0,03	2,28	-0,367	Algorithm converged.	-0,91	0,17	0,25	Algorithm converged.	0,03	2,27	0,3743	0,8316	3,93	Algorithm converged.	0,44	35,05			
	Positive	311	26,1	1	0,3	284	23,8	5	1,8	0,18	Algorithm converged.	0,02	1,55	-1,439	Algorithm converged.	-3,09	0,21	0,18	Algorithm converged.	0,02	1,55	0,1083		5,48	Algorithm converged.	0,64	46,58			
	Other	83	7	1	1,2	96	8	0	0	NE	*	Algorithm not converged.	NE	NE	1,205	Algorithm converged.	-1,14	3,55	NE	*	Algorithm not converged.	NE	NE	0,4637		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-eff-resp.sas, binary1-excel12.sas
 Output: t12-10-eff-resp-icu

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	833	804	769	728	698	663	638	603	554	519	489	451	422	392	375	351	335	318	303	290	272	262	249	241	228	211	191	134
Casirivimab/Imdevimab	1192	1192	878	836	788	739	690	636	598	541	498	455	420	392	356	336	315	299	282	257	237	225	218	209	201	195	183	180	165	107

Patients Censored

Placebo	0	360	366	369	371	376	378	380	382	386	388	389	390	391	392	393	395	397	398	399	400	402	402	403	404	405	411	422	473	602
Casirivimab/Imdevimab	0	314	315	316	318	319	322	322	325	326	327	328	330	332	334	335	335	336	338	339	340	342	344	346	347	348	349	359	404	509

Showing data observed through Day 29

Clinical cutoff: 19AUG2021

Program: f-km-plot.sas

Output: fl-1-km-plot-tsres.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: Time to COVID-19 symptoms resolution

Model: Stratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab													Placebo										Casirivimab/Imdevimab vs. Placebo					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio					
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	1192	100	683	57,299	509	42,701	6	6	7	11	10	12	1193	100	591	49,539	602	50,461	8	8	9	14	13	16	<.0001	1,272	1,139	1,42	Convergence criterion (GCONV=1E-8) satisfied.

Stratification factor = Country.

Test for Interaction based on Likelihood-Ratio test for Interaction with treatment effect.

* Indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: mFAS

ENDPOINT: Time to COVID-19 symptoms resolution

MODEL: --

STUDY: R10933-10987-COV-2067

Template Compliance/Mean

		Casirivimab/Imdevimab (N=1192)						Placebo (N=1193)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
All													
Baseline	All	1188	99,7	1114	93,8			1190	99,7	1101	92,5		
Day 2	All	1188	99,7	1030	86,7			1190	99,7	1018	85,5		
Day 3	All	1188	99,7	1043	87,8			1190	99,7	999	83,9		
Day 4	All	1187	99,6	1022	86,1			1190	99,7	988	83,0		
Day 5	All	1186	99,5	1005	84,7			1190	99,7	974	81,8		
Day 6	All	1185	99,4	1003	84,6			1189	99,7	965	81,2		
Day 7	All	1184	99,3	874	73,8			1189	99,7	834	70,1		
Day 8	All	1184	99,3	963	81,3			1188	99,6	933	78,5		
Day 9	All	1184	99,3	967	81,7			1188	99,6	915	77,0		
Day 10	All	1184	99,3	955	80,7			1187	99,5	908	76,5		
Day 11	All	1183	99,2	953	80,6			1184	99,2	895	75,6		
Day 12	All	1183	99,2	943	79,7			1184	99,2	893	75,4		
Day 13	All	1183	99,2	934	79,0			1184	99,2	897	75,8		
Day 14	All	1183	99,2	942	79,6			1182	99,1	886	75,0		
Day 15	All	1183	99,2	742	62,7			1181	99,0	704	59,6		
Day 16	All	1181	99,1	920	77,9			1181	99,0	873	73,9		
Day 17	All	1181	99,1	888	75,2			1181	99,0	858	72,7		
Day 18	All	1181	99,1	918	77,7			1181	99,0	868	73,5		
Day 19	All	1180	99,0	920	78,0			1181	99,0	858	72,7		
Day 20	All	1180	99,0	909	77,0			1181	99,0	875	74,1		
Day 21	All	1180	99,0	892	75,6			1180	98,9	862	73,1		
Day 22	All	1179	98,9	899	76,3			1178	98,7	863	73,3		
Day 23	All	1178	98,8	899	76,3			1177	98,7	849	72,1		
Day 24	All	1178	98,8	880	74,7			1177	98,7	835	70,9		
Day 25	All	1178	98,8	864	73,3			1177	98,7	841	71,5		
Day 26	All	1178	98,8	878	74,5			1177	98,7	834	70,9		
Day 27	All	1178	98,8	861	73,1			1175	98,5	838	71,3		

Day 28	All	1177	98,7	843	71,6			1175	98,5	809	68,9		
Day 29	All	1175	98,6	554	47,1			1173	98,3	534	45,5		
Day 30	All	1174	98,5	27	2,3			1173	98,3	19	1,6		
Day 31	All	1174	98,5	2	0,2			1172	98,2	5	0,4		
Day 32	All	1172	98,3	1	0,1			1172	98,2	3	0,3		
Day 33	All	1172	98,3	1	0,1			1171	98,2	2	0,2		
Day 34	All	1172	98,3	0	0,0			1171	98,2	2	0,2		
Day 44	All	1172	98,3	1	0,1			1169	98,0	0	0,0		
Day 51	All	1172	98,3	1	0,1			1169	98,0	1	0,1		
Day 113	All	1167	97,9	1	0,1			1158	97,1	0	0,0		
Day 120	All	1161	97,4	0	0,0			1152	96,6	1	0,1		

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

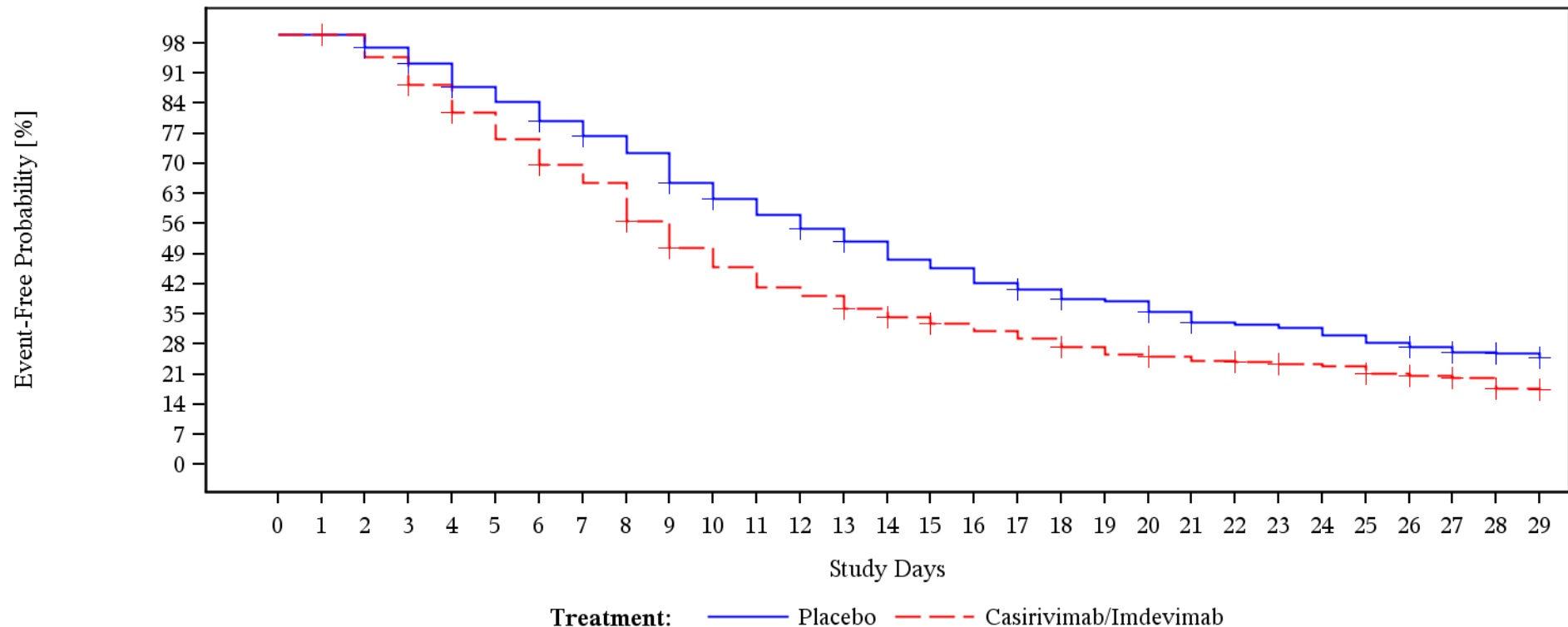
² mean: descriptive statistics - absolute values

Clinical cut-off: 19AUG2021

Program: t-eff-mean.sas

Output: t14-5-eff-mean-overall-tsres.xlsx

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

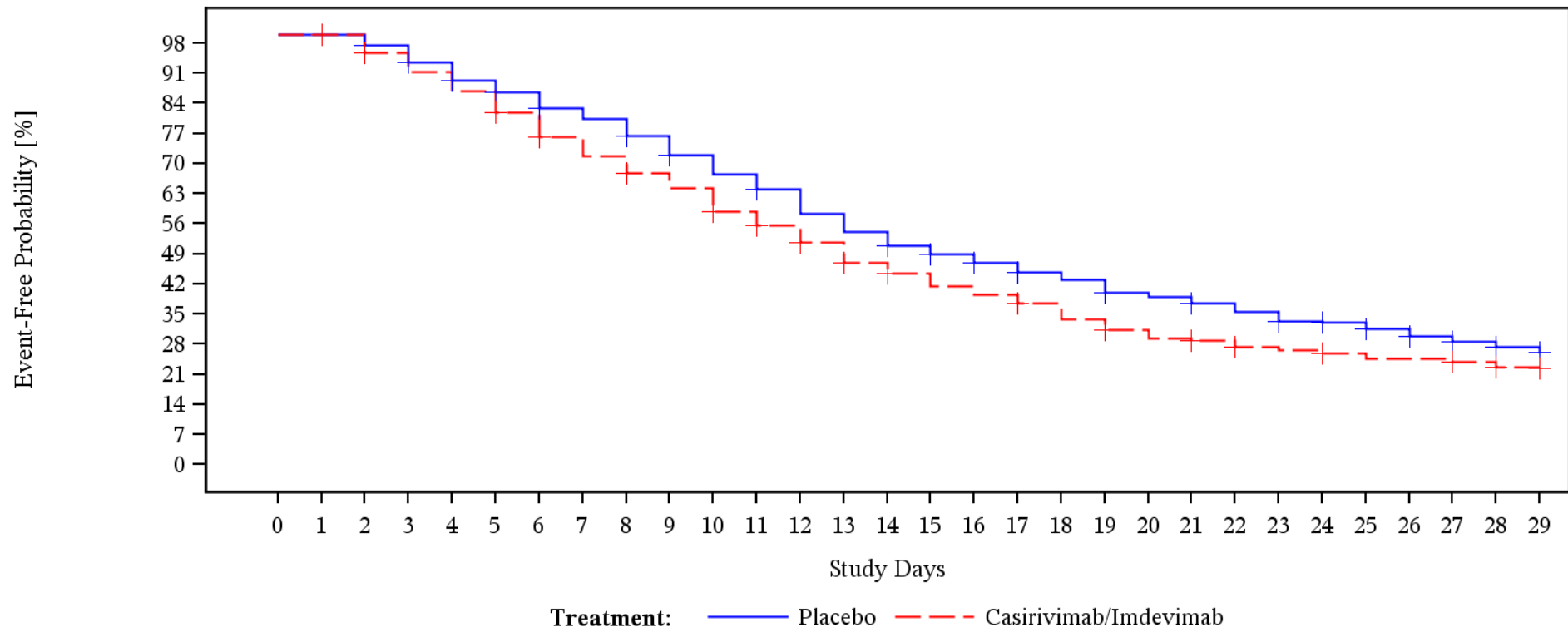
Placebo	580	580	374	361	346	325	312	294	280	265	238	222	209	196	185	170	163	150	144	135	133	124	114	112	110	104	98	91	82	58
Casirivimab/Imdevimab	579	579	406	385	358	330	305	280	263	225	199	182	163	155	142	134	127	120	113	104	97	94	91	89	85	83	76	73	68	48

Patients Censored

Placebo	0	206	208	209	210	210	211	213	213	215	217	217	218	219	219	219	219	220	221	221	222	223	223	223	223	223	226	231	254	310
Casirivimab/Imdevimab	0	173	173	174	176	176	177	177	179	180	180	180	180	181	182	183	183	183	185	185	186	186	187	189	189	190	191	194	206	253

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

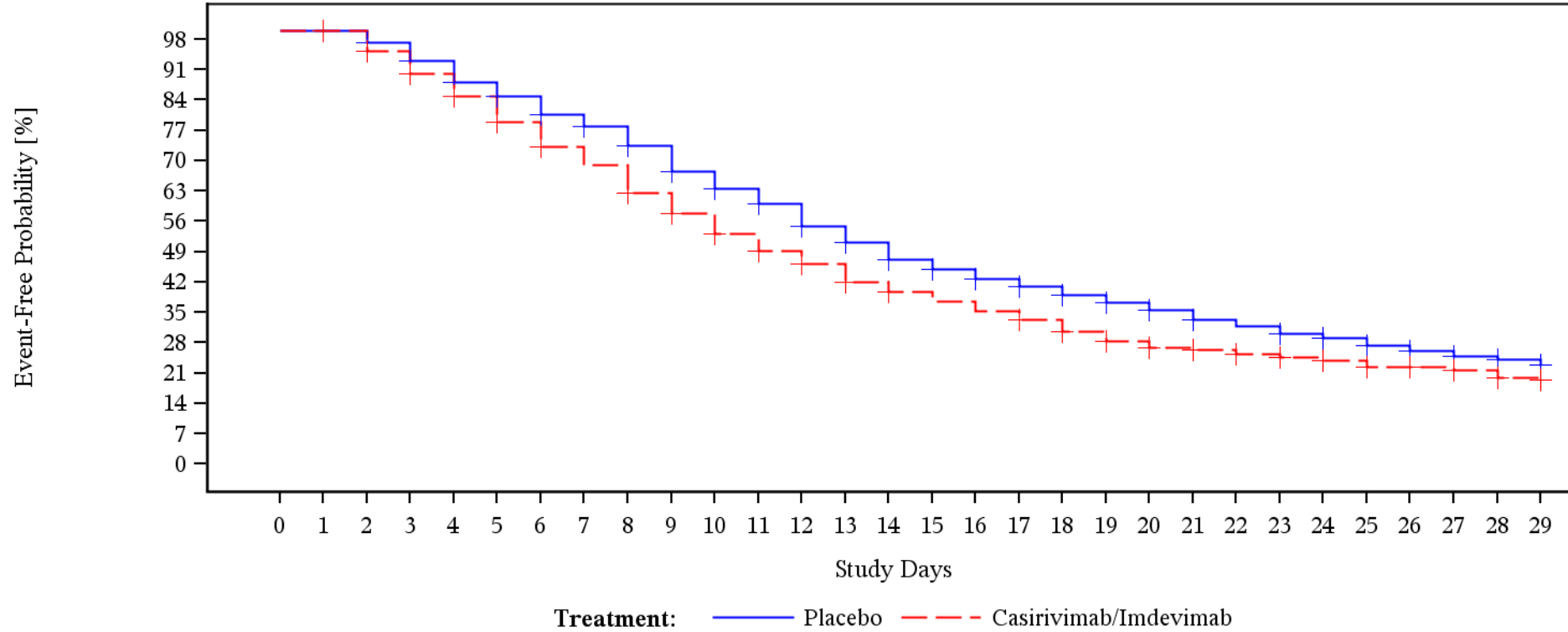
Placebo	613	613	459	443	423	403	386	369	358	338	316	297	280	255	237	222	212	201	191	183	170	166	158	150	139	137	130	120	109	76
Casirivimab/Imdevimab	613	613	472	451	430	409	385	356	335	316	299	273	257	237	214	202	188	179	169	153	140	131	127	120	116	112	107	107	97	59

Patients Censored

Placebo	0	154	158	160	161	166	167	167	169	171	171	172	172	172	173	174	176	177	177	178	178	179	179	180	181	182	185	191	219	292
Casirivimab/Imdevimab	0	141	142	142	142	143	145	145	146	146	147	148	150	151	152	152	152	153	153	154	154	156	157	157	158	158	158	165	198	256

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

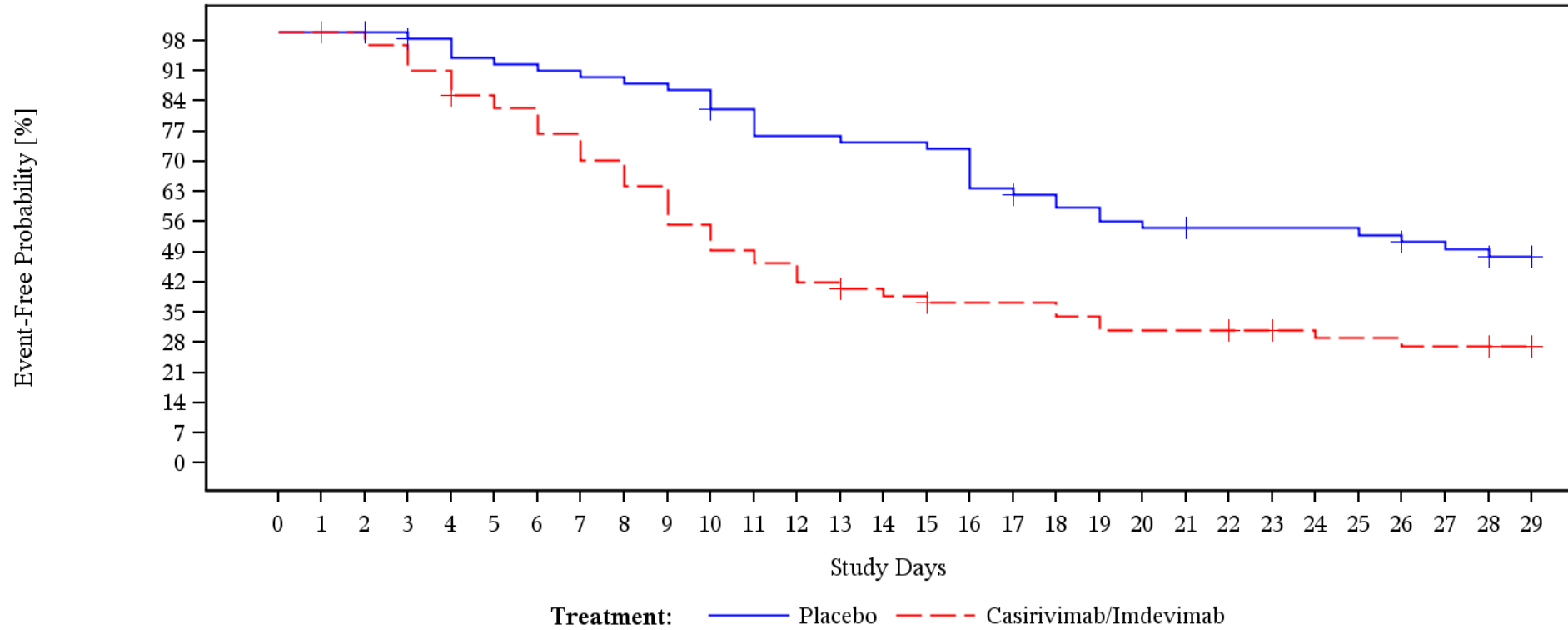
Placebo	1051	1051	743	718	686	648	620	587	565	531	485	454	429	391	364	334	318	300	286	271	258	246	229	219	206	198	186	172	154	106
Casirivimab/Imdevimab	1043	1043	785	747	705	663	616	568	535	483	446	408	376	351	318	300	282	266	250	227	210	198	192	184	177	172	160	158	143	92

Patients Censored

Placebo	0	308	312	313	315	320	322	324	326	329	330	331	332	333	334	335	337	338	339	340	341	342	342	343	344	345	350	360	403	504
Casirivimab/Imdevimab	0	258	259	260	261	262	265	265	268	269	270	271	273	274	276	276	276	277	279	280	281	283	284	285	286	287	288	298	337	427

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

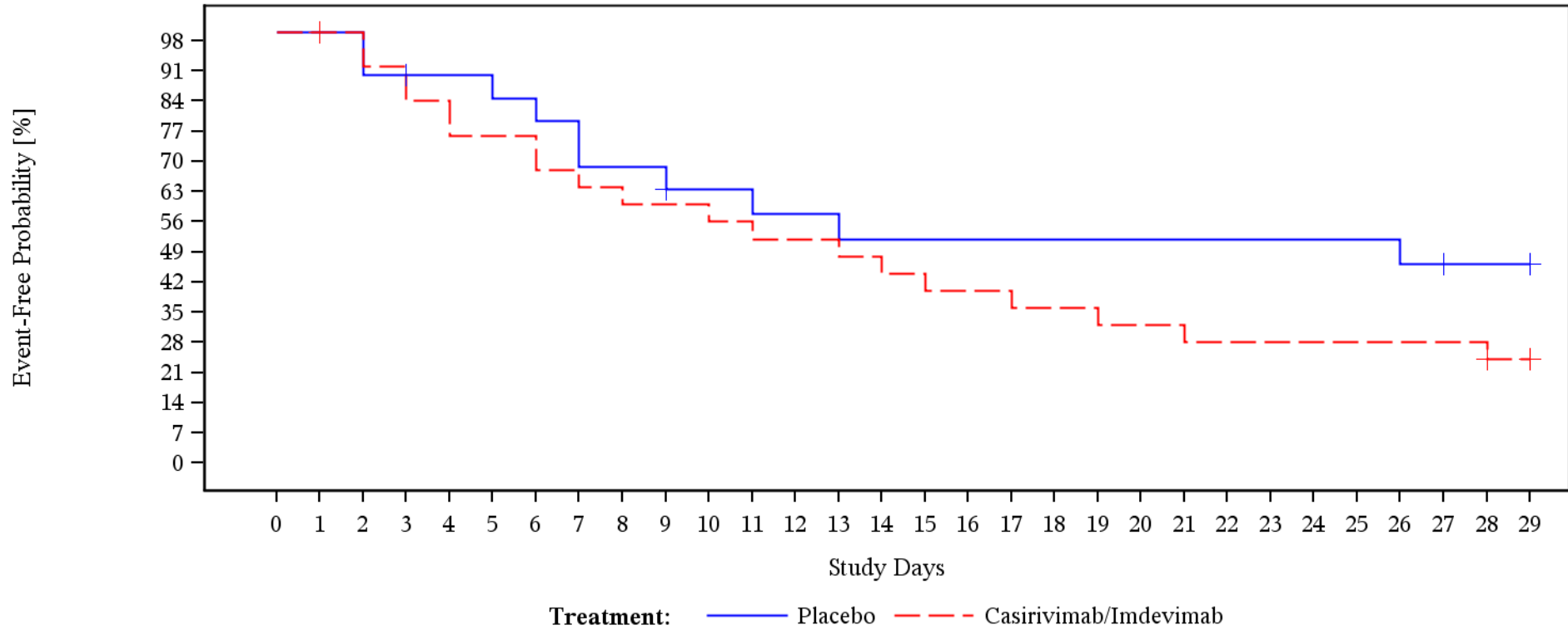
Placebo	108	108	70	68	66	63	62	61	60	59	58	54	50	50	49	49	48	42	40	38	36	35	34	34	34	34	33	31	30	21
Casirivimab/Imdevimab	100	100	68	66	62	57	55	51	47	43	37	33	31	28	26	25	23	23	23	21	19	19	19	18	17	16	16	15	15	10

Patients Censored

Placebo	0	38	40	41	41	41	41	41	41	41	42	42	42	42	42	42	42	43	43	43	43	44	44	44	44	44	45	45	53	74	
Casirivimab/Imdevimab	0	32	32	32	33	33	33	33	33	33	33	33	33	34	34	35	35	35	35	35	35	35	35	36	37	37	37	37	37	42	52

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

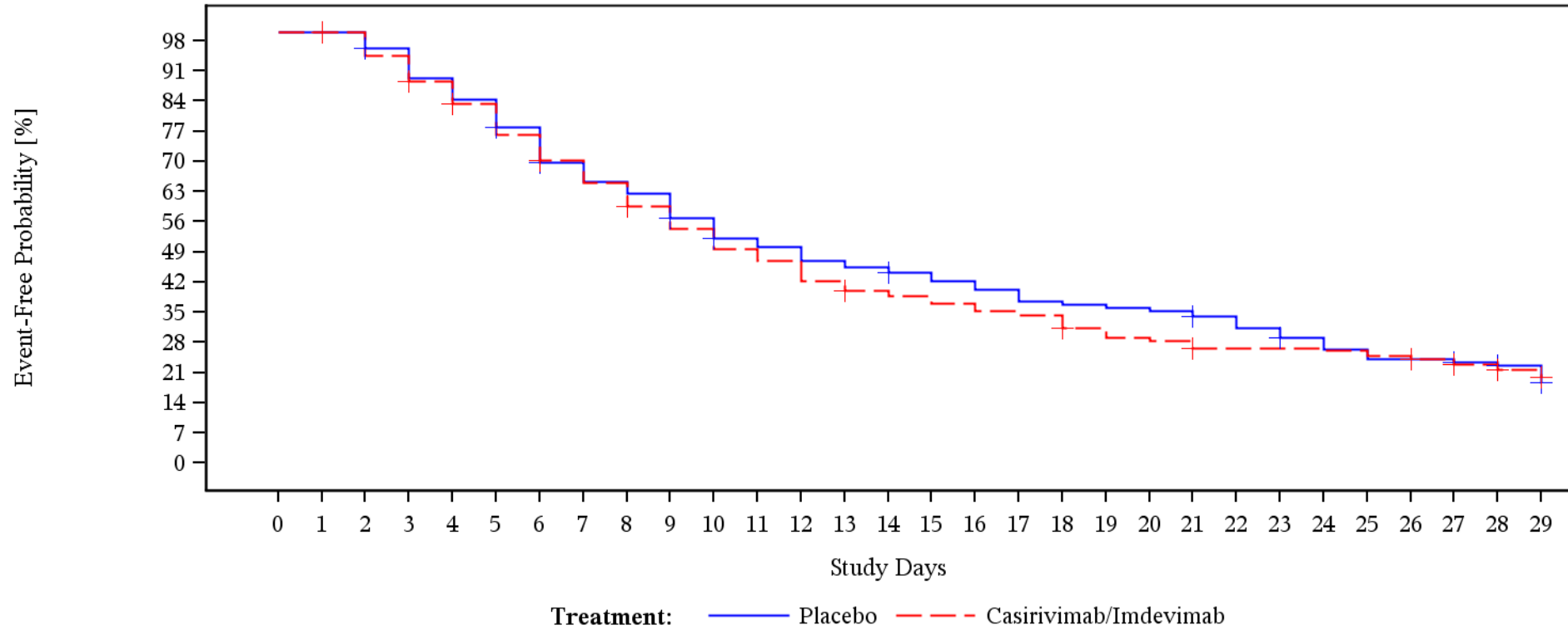
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
Placebo	34	34	20	18	17	17	16	15	13	13	11	11	10	10	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	7	7
Casirivimab/Imdevimab	49	49	25	23	21	19	19	17	16	15	15	14	13	13	12	11	10	10	9	9	8	8	7	7	7	7	7	7	7	5	

Patients Censored

		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
Placebo	0	14	14	15	15	15	15	15	15	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16	17	17	24
Casirivimab/Imdevimab	0	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	25	30	

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

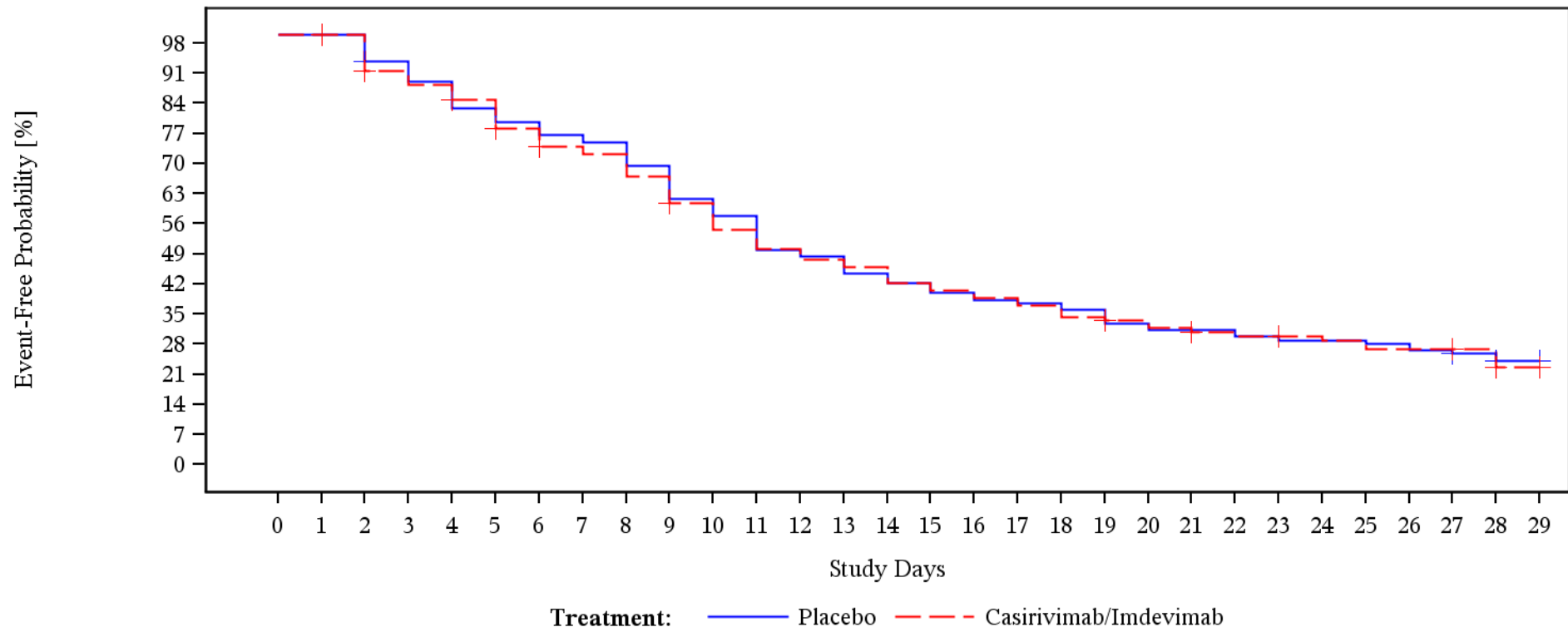
Placebo	242	242	161	153	142	134	122	108	101	97	87	78	75	70	68	65	62	59	55	54	53	52	49	45	41	37	34	32	30	23
Casirivimab/Imdevimab	260	260	182	172	160	150	137	125	116	104	95	87	82	74	69	67	64	61	59	53	49	48	44	44	44	43	41	39	35	24

Patients Censored

Placebo	0	81	83	83	83	85	86	86	86	87	89	89	89	89	90	90	90	90	90	90	90	91	91	92	92	92	94	95	101	120
Casirivimab/Imdevimab	0	78	78	79	80	80	81	81	83	83	83	83	83	84	84	84	84	84	85	85	85	86	86	86	86	86	87	89	98	120

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

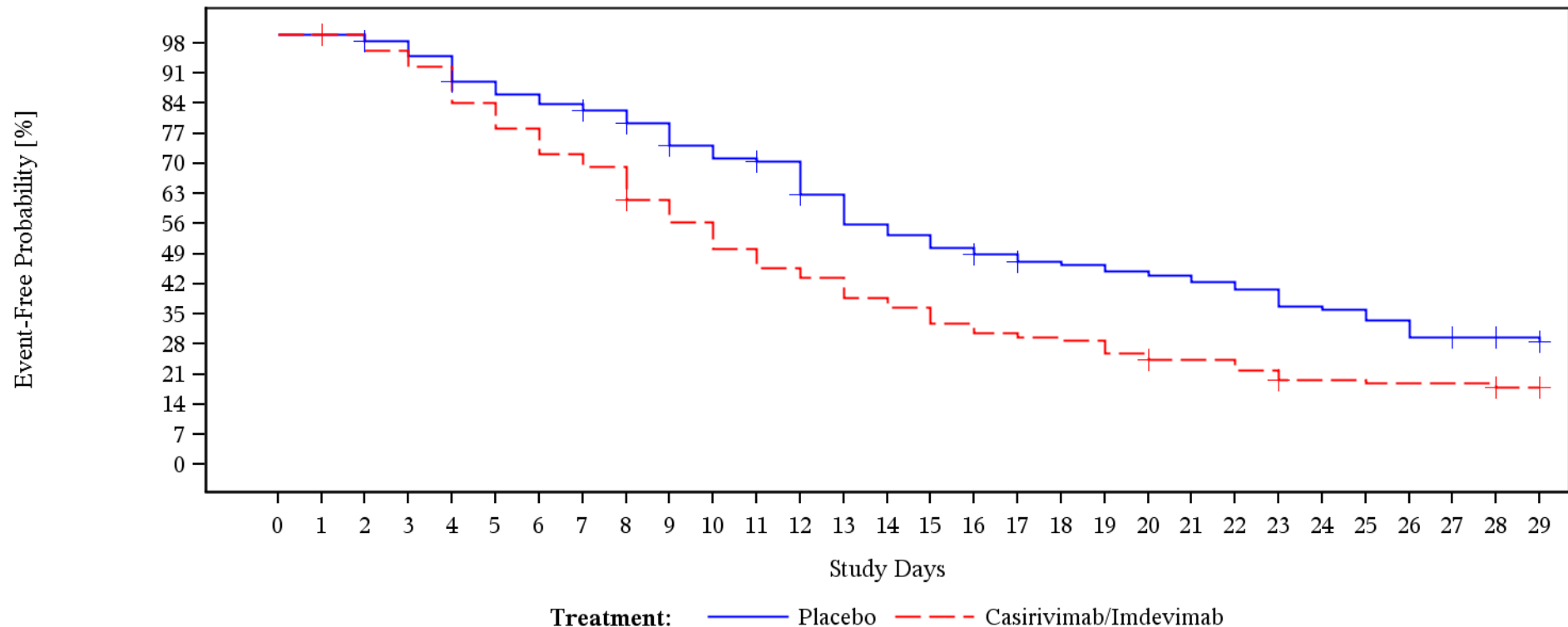
Placebo	183	183	129	120	114	106	102	98	96	89	79	74	64	62	57	54	51	49	48	46	42	40	40	38	37	37	36	34	30	13
Casirivimab/Imdevimab	158	158	120	109	105	100	91	85	83	77	69	62	57	54	52	48	46	44	42	39	37	35	33	32	31	30	28	28	25	16

Patients Censored

Placebo	0	54	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	58	73	86
Casirivimab/Imdevimab	0	38	39	39	40	41	42	42	42	43	43	43	43	43	43	43	43	43	43	44	44	45	45	46	46	46	46	49	54	70

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

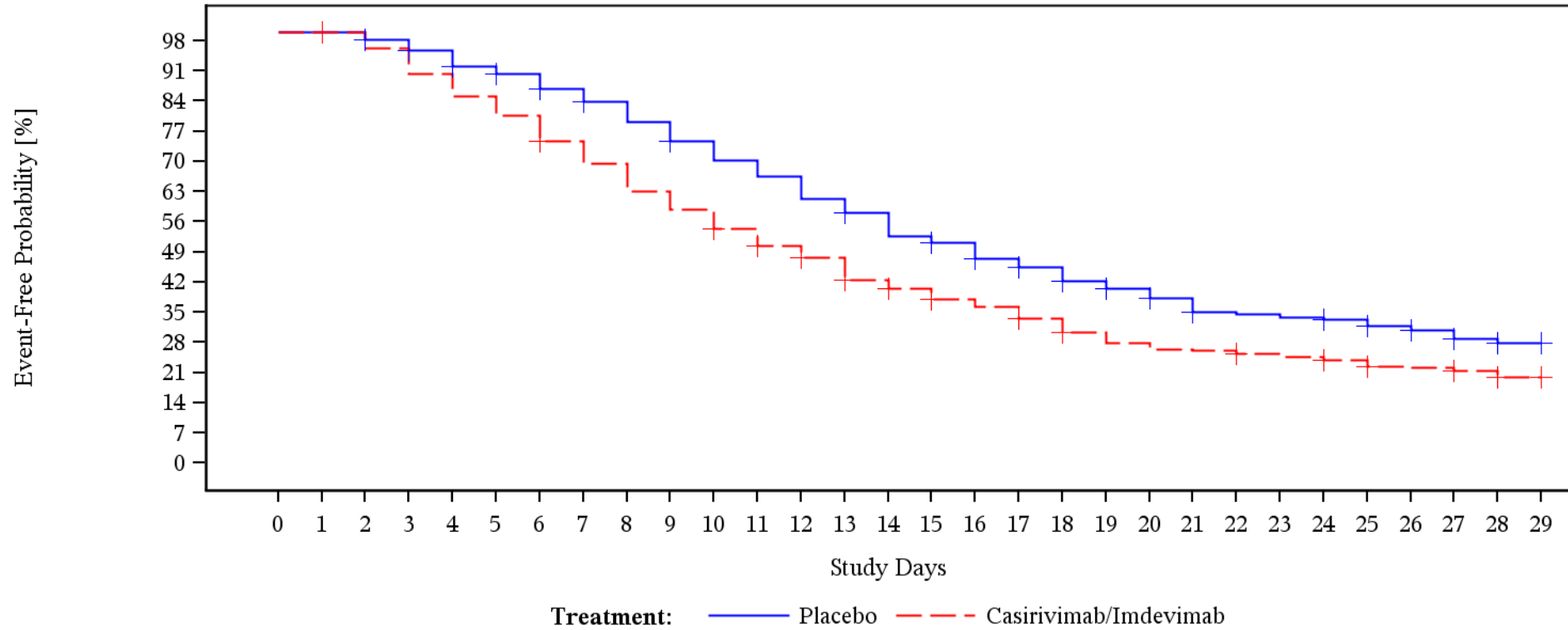
Placebo	205	205	139	135	130	121	117	114	111	106	98	94	92	81	72	69	65	62	59	58	56	55	53	51	46	45	42	37	33	28
Casirivimab/Imdevimab	183	183	133	128	123	112	104	96	92	81	74	66	60	57	51	48	43	40	39	38	34	31	31	28	24	24	23	23	23	13

Patients Censored

Placebo	0	66	68	68	69	69	69	70	71	72	72	73	74	74	74	74	75	76	76	76	76	76	76	76	76	76	76	76	80	85	112	
Casirivimab/Imdevimab	0	50	50	50	50	50	50	50	51	51	51	51	51	51	51	51	51	51	51	51	51	52	52	52	53	53	53	53	53	53	62	75

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

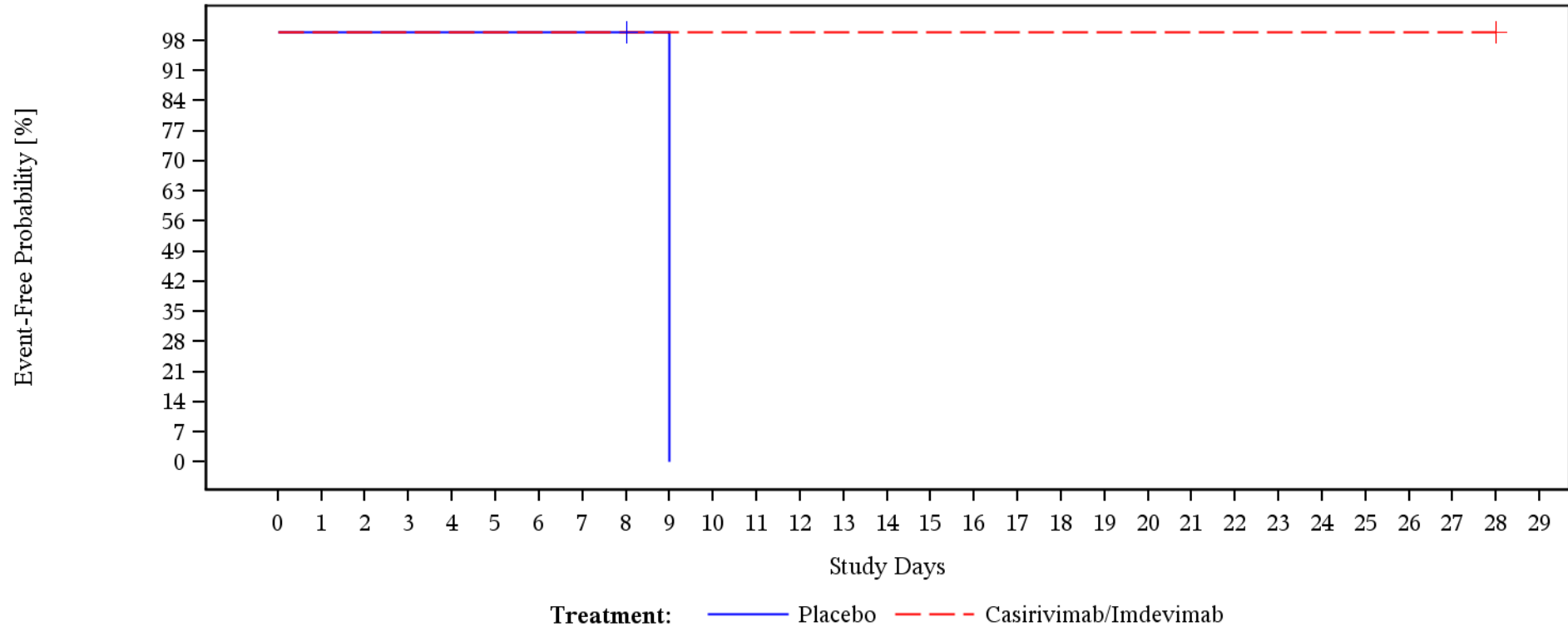
Placebo	561	561	402	394	381	365	355	341	328	310	290	273	258	238	225	204	197	181	173	160	152	143	130	128	125	122	116	108	98	70
Casirivimab/Imdevimab	590	590	442	426	399	376	357	329	306	278	259	239	220	206	183	172	161	153	141	126	116	110	109	104	101	97	90	89	81	54

Patients Censored

Placebo	0	159	160	163	164	167	168	169	169	171	171	171	171	172	172	173	174	175	176	177	178	179	179	179	180	181	185	188	213	283
Casirivimab/Imdevimab	0	148	148	148	148	148	149	149	149	149	150	151	153	154	156	157	157	158	159	159	159	159	161	161	162	163	163	168	189	243

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=Unknown



Patients At Risk

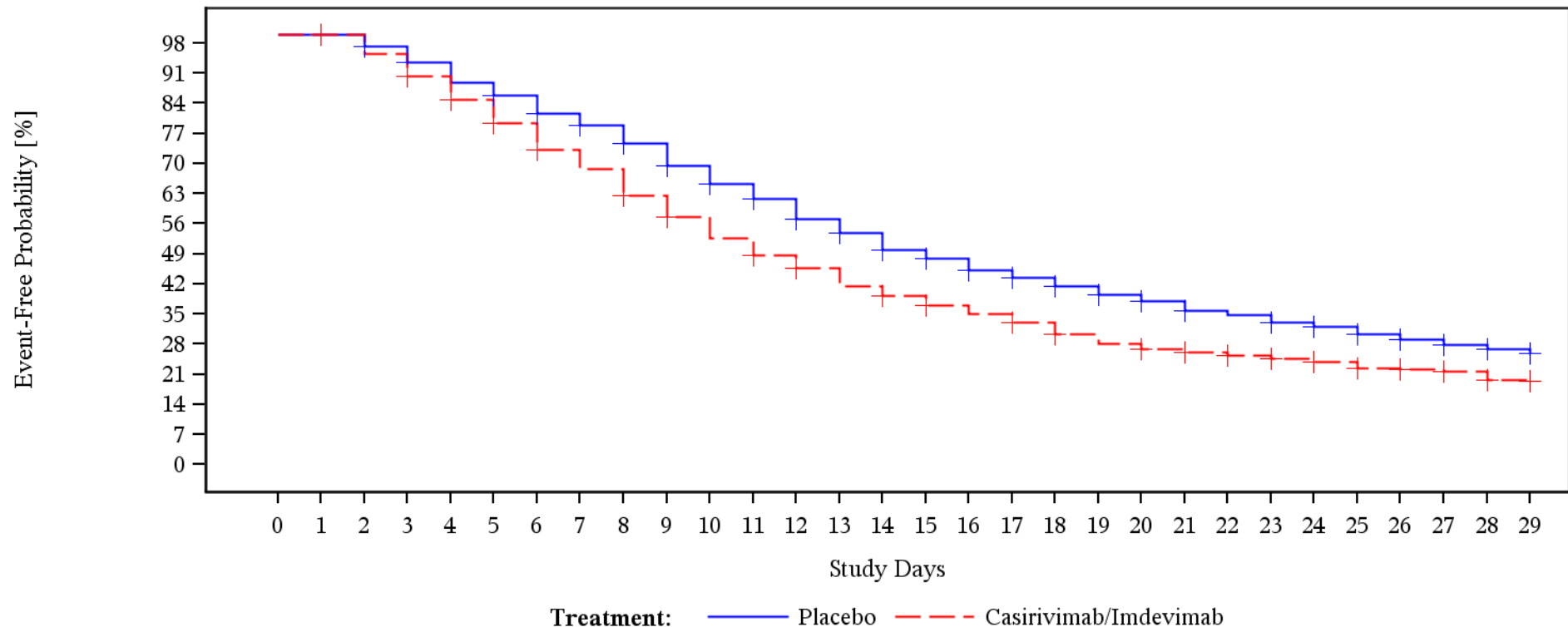
Placebo	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Casirivimab/Imdevimab	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0

Patients Censored

Placebo	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
Casirivimab/Imdevimab	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

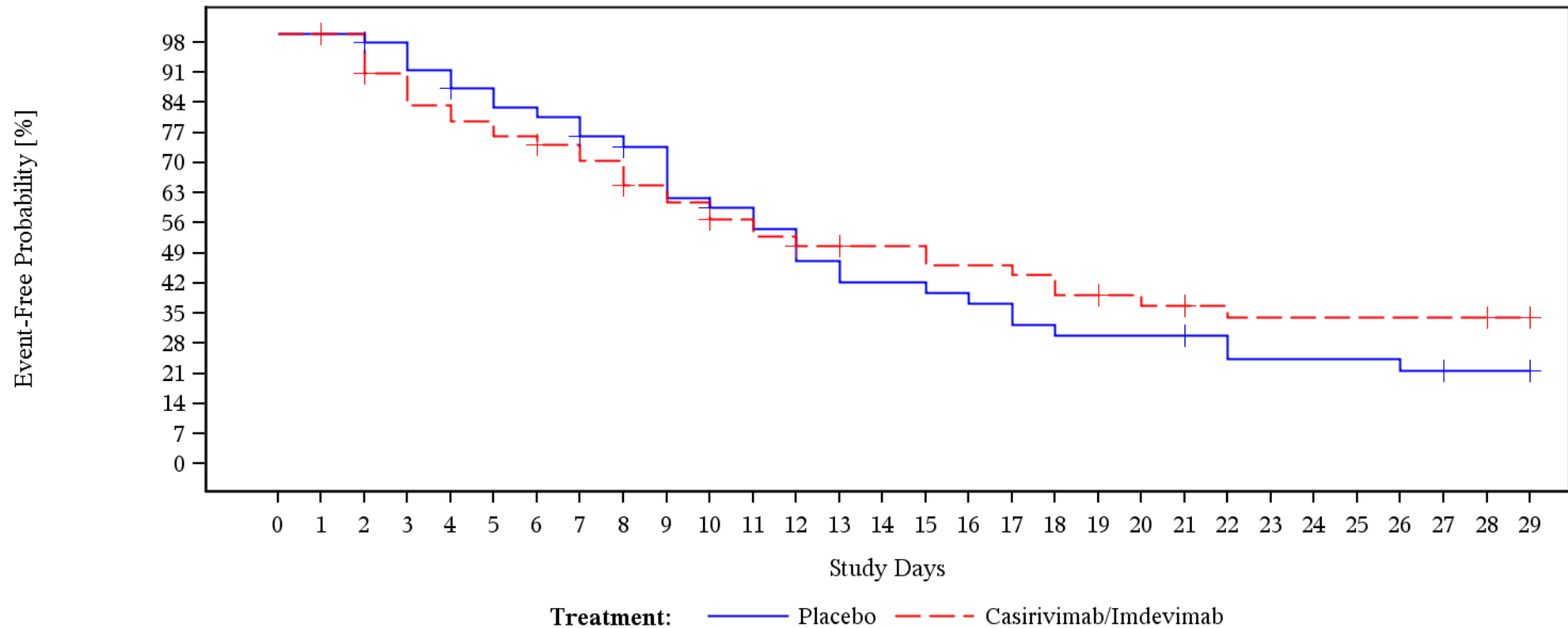
Placebo	1112	1112	784	758	726	689	661	627	605	572	528	495	467	432	405	375	359	336	322	306	291	278	261	253	240	232	219	203	184	127
Casirivimab/Imdevimab	1116	1116	823	787	743	696	649	597	561	508	467	427	394	368	334	314	295	279	263	240	221	210	204	196	188	182	170	167	152	101

Patients Censored

Placebo	0	328	332	335	335	340	342	343	344	348	349	350	351	352	353	354	356	358	359	360	361	362	362	363	364	365	371	381	432	554
Casirivimab/Imdevimab	0	293	293	294	296	297	299	299	301	302	302	303	304	304	306	307	307	308	310	310	311	312	314	316	317	318	319	329	367	466

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Country=MEX



Patients At Risk

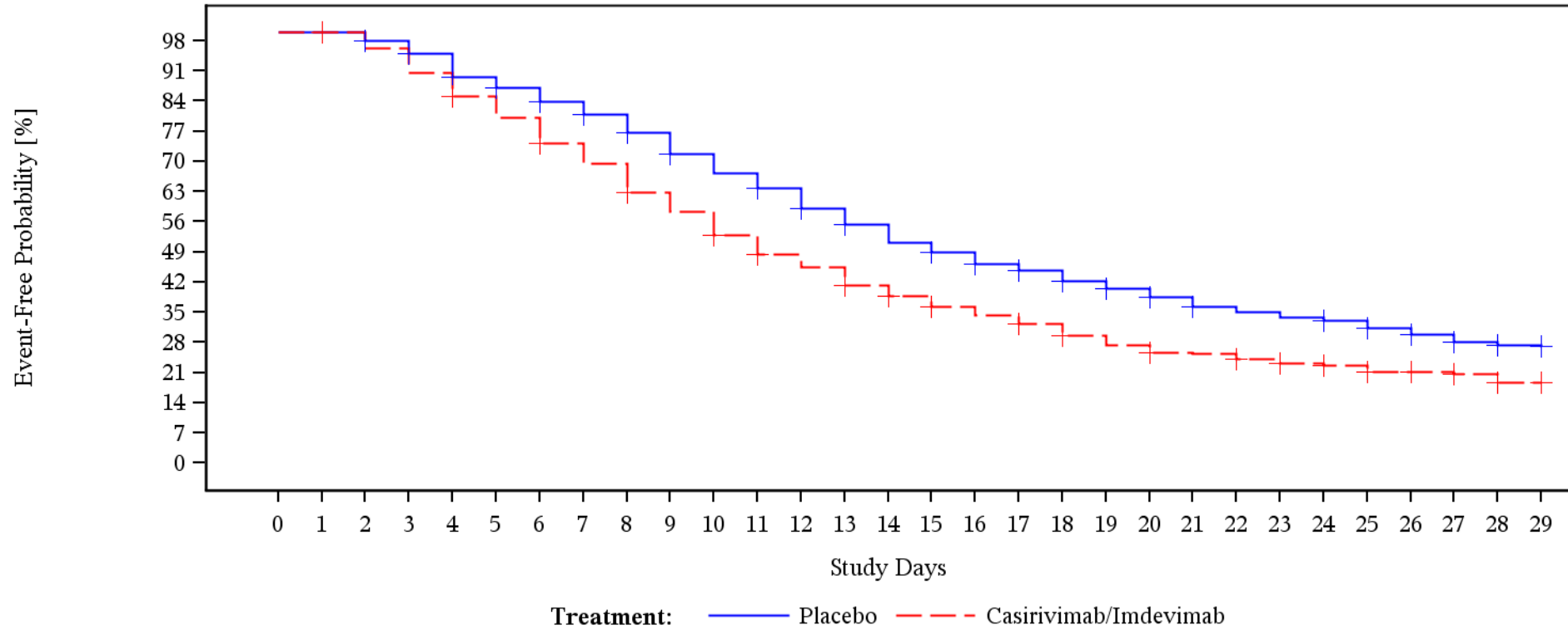
Placebo	81	81	49	46	43	39	37	36	33	31	26	24	22	19	17	17	16	15	13	12	12	12	11	9	9	9	9	8	7	7
Casirivimab/Imdevimab	76	76	55	49	45	43	41	39	37	33	31	28	26	24	22	22	20	20	19	17	16	15	14	13	13	13	13	13	13	6

Patients Censored

Placebo	0	32	34	34	36	36	36	37	38	38	39	39	39	39	39	39	39	39	39	39	39	40	40	40	40	40	40	40	41	41	48
Casirivimab/Imdevimab	0	21	22	22	22	22	23	23	24	24	25	25	26	28	28	28	28	28	28	29	29	30	30	30	30	30	30	30	30	37	43

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

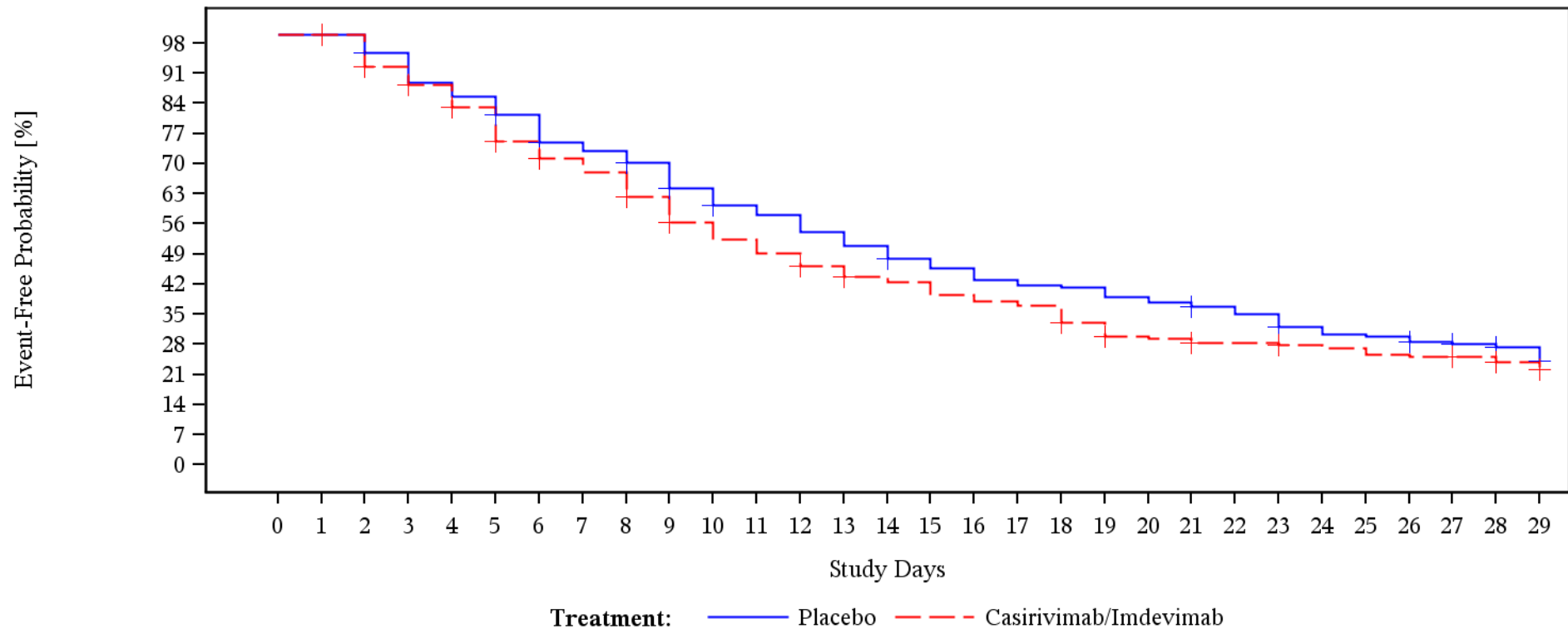
Placebo	813	813	578	563	543	510	493	474	455	430	399	375	354	327	305	282	269	252	242	228	217	206	192	186	179	174	164	151	135	91
Casirivimab/Imdevimab	798	798	607	585	549	515	485	447	419	378	351	317	290	271	245	228	213	201	188	172	159	148	146	137	131	126	118	116	108	70

Patients Censored

Placebo	0	235	238	241	243	246	247	249	250	253	253	254	255	256	256	257	259	261	262	263	264	265	265	265	266	267	272	280	320	410
Casirivimab/Imdevimab	0	191	191	191	192	192	194	194	195	195	196	197	197	198	200	201	201	202	203	203	204	204	206	207	208	209	210	215	243	313

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

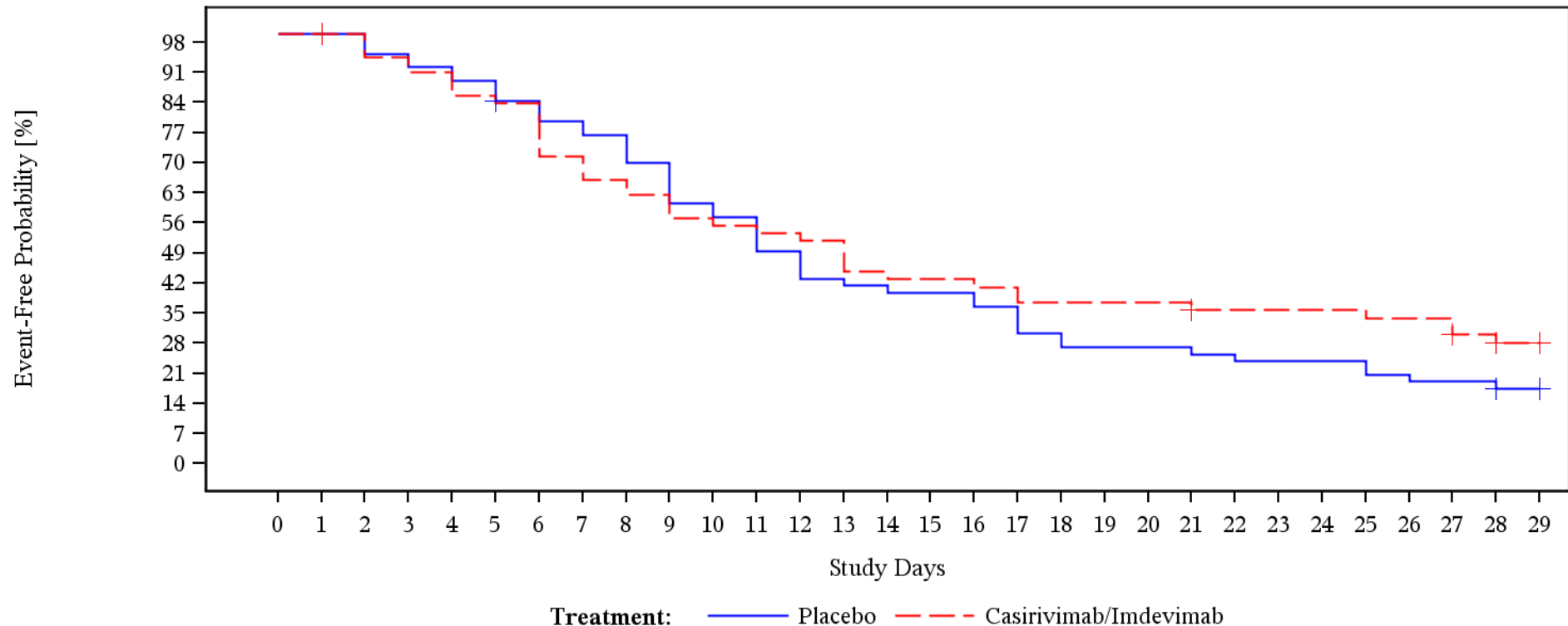
Placebo	284	284	191	180	167	161	152	139	135	129	117	108	104	97	91	85	81	76	74	73	69	67	64	61	55	52	51	48	44	34
Casirivimab/Imdevimab	311	311	215	198	188	176	158	149	142	128	115	107	100	92	86	84	78	75	73	64	57	56	53	53	51	50	47	46	42	27

Patients Censored

Placebo	0	93	96	96	96	97	98	98	99	100	102	102	102	102	103	103	103	103	103	103	103	104	104	105	105	105	106	109	118	148	
Casirivimab/Imdevimab	0	96	97	98	99	100	101	101	103	104	104	104	106	107	107	107	107	107	107	108	109	109	110	110	111	111	111	111	115	128	153

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Time to COVID-19 symptoms resolution
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	96	96	64	61	59	57	53	50	48	44	38	36	31	27	26	25	25	23	19	17	17	17	16	15	15	15	13	12	12	9
Casirivimab/Imdevimab	83	83	56	53	51	48	47	40	37	35	32	31	30	29	25	24	24	23	21	21	21	21	19	19	19	19	18	18	15	10

Patients Censored

Placebo	0	32	32	32	32	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	35	44		
Casirivimab/Imdevimab	0	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	28	28	28	28	28	28	29	33	43

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-1-km-plot-subgrp-tsres.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: Time to COVID-19 symptoms resolution

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					Interaction Test
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		p-value	Hazard Ratio	95% Lower CL	95% Upper CL	
All	n/a	1192	100	683	57,299	509	42,701	6	6	7	11	10	12	1193	100	591	49,539	602	50,461	8	8	9	14	13	16	<.0001	1,268	1,136	1,416	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	579	48,574	326	56,304	253	43,696	6	5	6	10	9	11	580	48,617	270	46,552	310	53,448	8	7	9	14	12	16	0,0001	1,357	1,154	1,595	Convergence criterion (GCONV=1E-8) satisfied.	0,2265
	Female	613	51,426	357	58,238	256	41,762	7	6	8	13	12	14	613	51,383	321	52,365	292	47,635	9	8	10	15	13	17	0,0165	1,197	1,029	1,391	Convergence criterion (GCONV=1E-8) satisfied.	
Age	18-64	1043	87,5	616	59,06	427	40,94	6	6	7	11	10	12	1051	88,097	547	52,046	504	47,954	8	7	9	14	13	15	0,0009	1,208	1,076	1,355	Convergence criterion (GCONV=1E-8) satisfied.	0,0462
	65-74	100	8,389	48	48	52	52	7	4	8	10	9	15	108	9,053	34	31,481	74	68,519	13	10	16	27	17	NE	0,0008	2,073	1,332	3,227	Convergence criterion (GCONV=1E-8) satisfied.	
	>=75	49	4,111	19	38,776	30	61,224	6	2	10	13	6	21	34	2,85	10	29,412	24	70,588	7	2	13	26	7	NE	0,2065	1,619	0,752	3,486	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline viral load categories	<=10^5 copies/mL	260	21,812	140	53,846	120	46,154	6	5	7	10	9	12	242	20,285	122	50,413	120	49,587	6	5	7	12	9	15	0,6931	1,048	0,822	1,337	Convergence criterion (GCONV=1E-8) satisfied.	0,0747
	>10^5 copies/mL - <=10^6 copies/mL	158	13,255	88	55,696	70	44,304	6	5	8	12	10	15	183	15,339	97	53,005	86	46,995	8	5	9	12	10	15	0,8455	1,028	0,77	1,372	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: Time to COVID-19 symptoms resolution

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
	>10^6 copies/mL - <=10^7 copies/mL	183	15,352	108	59,016	75	40,984	6	5	8	11	9	13	205	17,184	93	45,366	112	54,634	9	7	12	16	13	22	0,0014	1,549	1,173	2,047	Convergence criterion (GCONV=1E-8) satisfied.		
	>10^7 copies/mL	590	49,497	347	58,814	243	41,186	6	6	7	12	10	13	561	47,024	278	49,554	283	50,446	9	8	10	16	14	18	<.0001	1,381	1,179	1,617	Convergence criterion (GCONV=1E-8) satisfied.		
	Unknown	1	0,084	0	0	1	100	NE	NE	NE	NE	NE	NE	2	0,168	1	50	1	50	9	NE	NE	9	NE	NE	0,3173	0	0	NE	*	WARNING: Iteration limit reached without convergence.	
Country	USA	1116	93,624	650	58,244	466	41,756	6	6	7	11	10	12	1112	93,21	558	50,18	554	49,82	8	8	9	14	14	16	<.0001	1,299	1,16	1,455	Convergence criterion (GCONV=1E-8) satisfied.	0,0884	
	MEX	76	6,376	33	43,421	43	56,579	6	3	9	15	9	22	81	6,79	33	40,741	48	59,259	8	4	9	12	9	17	0,5363	0,862	0,532	1,398	Convergence criterion (GCONV=1E-8) satisfied.		
Race/ethnicity	White	979	82,131	579	59,142	400	40,858	6	6	7	11	11	12	984	82,481	503	51,118	481	48,882	8	8	9	14	13	16	<.0001	1,263	1,121	1,424	Convergence criterion (GCONV=1E-8) satisfied.	0,6711	
	Black or African American	55	4,614	24	43,636	31	56,364	4,5	3	8	9	6	18	51	4,275	17	33,333	34	66,667	8	3	14	16	10	NE	0,1521	1,552	0,832	2,895	Convergence criterion (GCONV=1E-8) satisfied.		
	Asian/American Indian Alaska Native/Native Hawaiian or other Pacific Islander	85	7,131	43	50,588	42	49,412	5	4	7	10	7	15	70	5,868	30	42,857	40	57,143	11	6	12	16	12	25	0,1368	1,41	0,884	2,25	Convergence criterion (GCONV=1E-8) satisfied.		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: Time to COVID-19 symptoms resolution

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
	Unknown/Not Reported	73	6,124	37	50,685	36	49,315	7	4	9	13	9	18	88	7,376	41	46,591	47	53,409	7	4	9	12	9	18	0,6987	1,089	0,698	1,701	Convergence criterion (GCONV=1E-8) satisfied.		
Baseline serostatus	Negative	798	66,946	485	60,777	313	39,223	6	6	7	11	10	12	813	68,148	403	49,569	410	50,431	9	8	10	15	14	17	<.0001	1,374	1,204	1,569	Convergence criterion (GCONV=1E-8) satisfied.	0,2196	
	Positive	311	26,091	158	50,804	153	49,196	6	5	7	11	9	14	284	23,806	136	47,887	148	52,113	7	6	9	14	12	17	0,2147	1,151	0,915	1,448	Convergence criterion (GCONV=1E-8) satisfied.		
	Other	83	6,963	40	48,193	43	51,807	6	4	8	13	8	17	96	8,047	52	54,167	44	45,833	8	5	9	11	9	16	0,3599	0,83	0,549	1,254	Convergence criterion (GCONV=1E-8) satisfied.		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

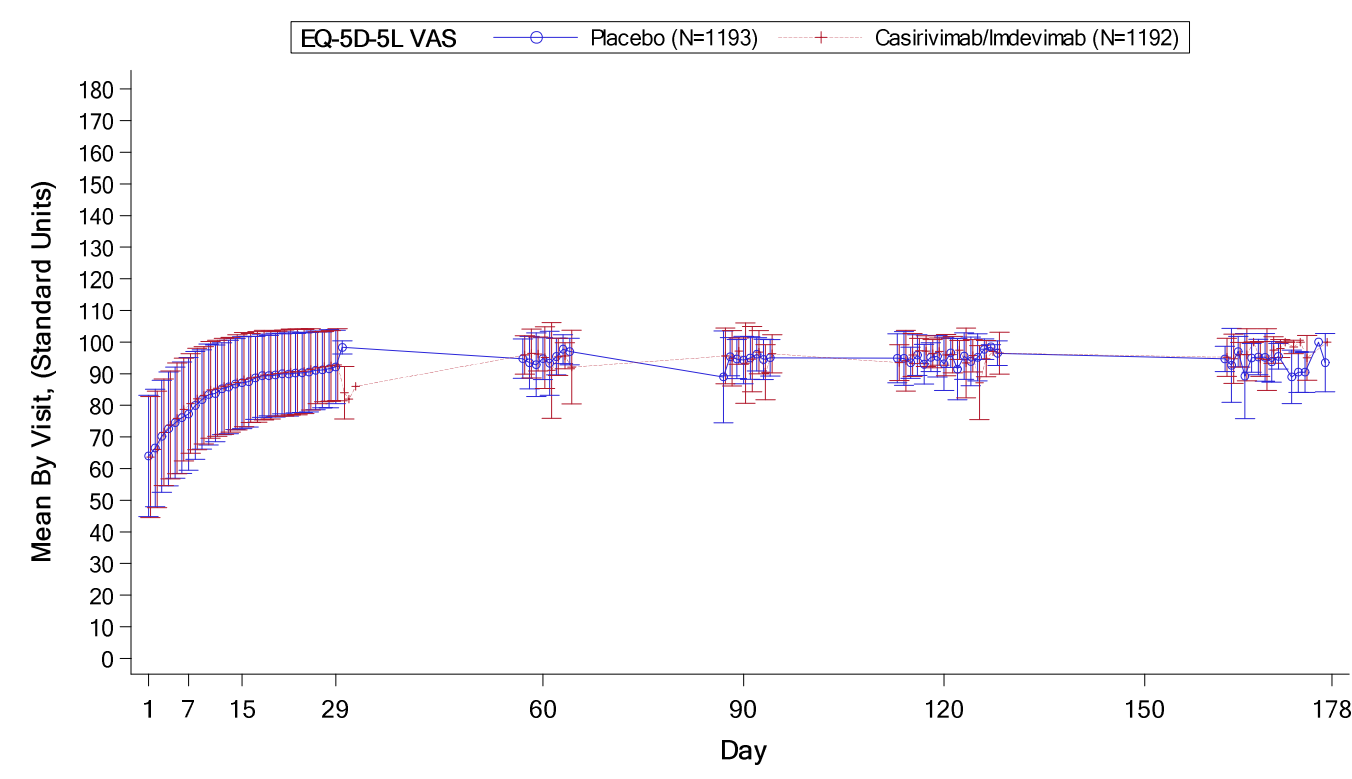
Clinical cut-off: 19Aug2021.

Datenschnitt 19.08.2021 (DCO2)

Wirksamkeit

PRO

Figure 2.2. Line plot of mean of EQ5D02-EQ VAS Score at each visit
Modified Full Analysis Set



Clinical cut-off: 19Aug2021

POPULATION: PRO Evaluable (mFAS)
 ENDPOINT: EQ-5D-5L VAS
 MODEL: Stratified analysis
 STUDY: R10933-10987-COV-2067
 Template Change from Baseline in EQ5D02-EQ VAS Score (Analysis of MMRM)

Endpoint	Name	Level	Casirivimab/Imdevimab					Placebo					Difference between Treatments (Casirivimab/Imdevimab vs. Placebo)					
			N			Statistics		N			Statistics		LSMeans ³	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/Method ⁴	
			Total	with baseline value	included in analysis ¹	LSMeans ²	SE (LSMeans)	Total	with baseline value	included in analysis ¹	LSMeans ²	SE (LSMeans)						
Change from Baseline in EQ5D02-EQ VAS Score	All	Day 29	1177	542	542	27,82	0,51	1176	516	516	27,30	0,52	0,52	0,73	-0,91	1,95	MFAS	adjusted

- 1) Patients with a value at baseline and at least one post-baseline value
- 2) LSMeans of change from baseline from MMRM (including all available records from all visits)
- 3) Contrasts from MMRM
- 4) Factors/Covariates: treatment, country, visit, treatment-by-visit interaction, baseline value. In addition, for the **total population**, adjusted for randomization stratification factors: country.
 Data as observed (no imputation of missing values)
 Covariance matrix: unstructured

Clinical cut-off: 19AUG2021

Program: t-eff-mmrm.sas

Output: t15-eff-mmrm-overall-eq5d0206.xlsx, t15-eff-mmrm-overall-eq5d0206.pdf

POPULATION: mFAS

ENDPOINT: EQ-5D-5L VAS

MODEL: --

STUDY: R10933-10987-COV-2067

Template Compliance/Mean

		Casirivimab/Imdevimab (N=1192)						Placebo (N=1193)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
Visit													
All													
Baseline	All	596	50,0	596	100,0	63,64	19,09	578	48,4	578	100,0	63,98	19,20
Day 2	All	596	50,0	5	0,8	55,60	15,45	578	48,4	9	1,6	54,89	25,91
Day 3	All	596	50,0	2	0,3	72,50	13,44	578	48,4	1	0,2	87,00	0,00
Day 4	All	596	50,0	4	0,7	55,50	35,78	578	48,4	5	0,9	51,00	25,65
Day 5	All	595	49,9	5	0,8	76,20	14,82	578	48,4	7	1,2	75,43	18,46
Day 6	All	594	49,8	143	24,1	78,91	16,83	577	48,4	148	25,6	75,17	19,69
Day 7	All	594	49,8	408	68,7	80,57	15,73	577	48,4	371	64,3	77,30	17,79
Day 8	All	594	49,8	16	2,7	73,94	20,70	577	48,4	13	2,3	78,92	18,23
Day 9	All	594	49,8	2	0,3	78,50	4,95	577	48,4	4	0,7	65,50	36,24
Day 10	All	594	49,8	0	0,0			577	48,4	1	0,2	90,00	0,00
Day 12	All	594	49,8	5	0,8	88,60	8,38	577	48,4	4	0,7	77,75	23,24
Day 13	All	594	49,8	6	1,0	71,00	29,62	577	48,4	7	1,2	90,14	4,10
Day 14	All	594	49,8	191	32,2	87,84	13,64	577	48,4	186	32,2	86,30	14,64
Day 15	All	594	49,8	350	58,9	88,11	14,89	576	48,3	320	55,6	87,17	14,52
Day 16	All	593	49,7	14	2,4	87,71	16,14	576	48,3	15	2,6	83,67	12,89
Day 17	All	593	49,7	0	0,0			576	48,3	3	0,5	94,67	9,24
Day 18	All	593	49,7	1	0,2	74,00	0,00	576	48,3	2	0,3	83,00	4,24
Day 19	All	592	49,7	0	0,0			576	48,3	1	0,2	100,00	0,00
Day 20	All	592	49,7	0	0,0			576	48,3	1	0,2	85,00	0,00
Day 21	All	592	49,7	0	0,0			576	48,3	1	0,2	73,00	0,00
Day 22	All	592	49,7	0	0,0			575	48,2	1	0,2	82,00	0,00
Day 23	All	592	49,7	9	1,5	91,22	16,99	574	48,1	0	0,0		
Day 24	All	592	49,7	4	0,7	91,25	8,54	574	48,1	5	0,9	85,00	20,45
Day 25	All	592	49,7	10	1,7	85,00	31,24	574	48,1	8	1,4	95,50	8,65
Day 26	All	592	49,7	20	3,4	94,00	11,09	574	48,1	15	2,6	84,40	24,35
Day 27	All	592	49,7	24	4,1	88,42	10,91	574	48,1	32	5,6	92,88	11,57
Day 28	All	591	49,6	199	33,7	92,77	10,69	574	48,1	193	33,6	91,60	10,96

Day 29	All	590	49,5	274	46,4	92,81	11,39	573	48,0	261	45,5	92,14	11,62
Day 57	All	587	49,2	11	1,9	95,91	6,07	571	47,9	12	2,1	94,75	6,24
Day 58	All	587	49,2	17	2,9	96,41	7,74	571	47,9	15	2,6	93,47	8,31
Day 59	All	587	49,2	18	3,1	96,22	5,35	571	47,9	12	2,1	92,83	10,10
Day 60	All	587	49,2	182	31,0	95,09	9,76	571	47,9	178	31,2	94,78	6,66
Day 61	All	587	49,2	24	4,1	90,33	15,88	571	47,9	25	4,4	93,04	10,21
Day 62	All	587	49,2	12	2,0	96,25	5,59	571	47,9	12	2,1	95,75	6,02
Day 63	All	587	49,2	6	1,0	95,67	4,13	571	47,9	11	1,9	98,09	4,59
Day 64	All	587	49,2	17	2,9	92,06	11,63	571	47,9	18	3,2	97,00	4,24
Day 87	All	585	49,1	10	1,7	95,60	8,80	569	47,7	10	1,8	89,00	14,53
Day 88	All	585	49,1	20	3,4	94,90	8,77	568	47,6	16	2,8	95,38	5,99
Day 89	All	585	49,1	23	3,9	97,13	4,12	568	47,6	25	4,4	94,64	6,15
Day 90	All	585	49,1	79	13,5	93,35	12,73	568	47,6	81	14,3	94,30	7,49
Day 91	All	585	49,1	42	7,2	94,60	10,30	567	47,5	42	7,4	94,98	6,73
Day 92	All	585	49,1	21	3,6	96,81	6,82	567	47,5	18	3,2	96,17	5,27
Day 93	All	585	49,1	11	1,9	90,45	8,73	567	47,5	12	2,1	94,50	6,40
Day 94	All	585	49,1	35	6,0	96,29	6,01	567	47,5	38	6,7	95,05	5,77
Day 113	All	585	49,1	21	3,6	93,48	5,65	566	47,4	25	4,4	94,88	7,73
Day 114	All	585	49,1	9	1,5	94,11	9,58	566	47,4	12	2,1	94,83	8,52
Day 115	All	585	49,1	19	3,2	95,95	6,75	566	47,4	7	1,2	93,43	4,93
Day 116	All	585	49,1	9	1,5	97,22	4,02	566	47,4	11	1,9	95,91	6,41
Day 117	All	585	49,1	7	1,2	97,14	4,88	566	47,4	5	0,9	93,00	6,24
Day 118	All	585	49,1	15	2,6	96,33	4,42	565	47,4	14	2,5	95,21	4,56
Day 119	All	585	49,1	23	3,9	97,00	4,34	565	47,4	30	5,3	95,53	6,55
Day 120	All	583	48,9	73	12,5	95,93	6,53	565	47,4	68	12,0	93,15	8,45
Day 121	All	583	48,9	29	5,0	96,00	5,76	565	47,4	20	3,5	96,60	4,58
Day 122	All	583	48,9	8	1,4	97,50	3,02	565	47,4	11	1,9	91,45	9,69
Day 123	All	583	48,9	5	0,9	93,40	10,99	565	47,4	12	2,1	95,58	7,30
Day 124	All	583	48,9	7	1,2	95,71	5,12	565	47,4	11	1,9	93,91	7,71
Day 125	All	583	48,9	7	1,2	87,14	11,68	565	47,4	13	2,3	95,15	7,45
Day 126	All	583	48,9	4	0,7	94,75	5,74	564	47,3	4	0,7	97,75	3,20
Day 127	All	583	48,9	1	0,2	97,00	0,00	563	47,2	2	0,4	98,50	0,71
Day 128	All	583	48,9	22	3,8	96,50	6,67	563	47,2	22	3,9	96,45	3,89
Day 162	All	532	44,6	10	1,9	95,20	6,01	519	43,5	5	1,0	95,60	3,65
Day 163	All	516	43,3	7	1,4	94,00	8,08	502	42,1	11	2,2	92,55	12,23
Day 164	All	496	41,6	4	0,8	96,00	3,92	481	40,3	5	1,0	97,00	4,80
Day 165	All	476	39,9	7	1,5	96,00	8,25	462	38,7	4	0,9	89,25	13,50
Day 166	All	457	38,3	2	0,4	100,00	0,00	441	37,0	2	0,5	94,50	6,36
Day 167	All	443	37,2	3	0,7	94,67	5,51	426	35,7	4	0,9	95,25	5,62
Day 168	All	391	32,8	6	1,5	94,50	9,77	373	31,3	5	1,3	95,20	7,56
Day 169	All	181	15,2	6	3,3	97,50	4,18	172	14,4	8	4,7	93,75	6,45
Day 170	All	102	8,6	2	2,0	98,00	2,83	95	8,0	4	4,2	96,00	4,08
Day 171	All	75	6,3	1	1,3	100,00	0,00	69	5,8	0	0,0		

Day 172	All	61	5,1	1	1,6	97,00	0,00	52	4,4	0	0,0		
Day 174	All	44	3,7	1	2,3	90,00	0,00	35	2,9	0	0,0		
Day 176	All	13	1,1	0	0,0			15	1,3	1	6,7	100,00	0,00
Day 177	All	9	0,8	1	11,1	100,00	0,00	10	0,8	2	20,0	93,50	9,19

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 19AUG2021

Program: t-eff-mean.sas

Output: t14-2-eff-mean-overall-eq5d0206_eq5dbl.xlsx

POPULATION: mFAS

ENDPOINT: Return to usual health

MODEL: --

STUDY: R10933-10987-COV-2067

Template Compliance/Mean

		Casirivimab/Imdevimab (N=1192)						Placebo (N=1193)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
Visit													
All													
Baseline	All	1188	99,7	790	66,5			1190	99,7	775	65,1		
Day 2	All	1188	99,7	7	0,6			1190	99,7	11	0,9		
Day 3	All	1188	99,7	4	0,3			1190	99,7	4	0,3		
Day 4	All	1187	99,6	6	0,5			1190	99,7	5	0,4		
Day 5	All	1186	99,5	9	0,8			1190	99,7	11	0,9		
Day 6	All	1185	99,4	179	15,1			1189	99,7	177	14,9		
Day 7	All	1184	99,3	642	54,2			1189	99,7	623	52,4		
Day 8	All	1184	99,3	42	3,5			1188	99,6	39	3,3		
Day 9	All	1184	99,3	27	2,3			1188	99,6	16	1,3		
Day 10	All	1184	99,3	14	1,2			1187	99,5	21	1,8		
Day 11	All	1183	99,2	5	0,4			1184	99,2	4	0,3		
Day 12	All	1183	99,2	11	0,9			1184	99,2	7	0,6		
Day 13	All	1183	99,2	12	1,0			1184	99,2	13	1,1		
Day 14	All	1183	99,2	267	22,6			1182	99,1	266	22,5		
Day 15	All	1183	99,2	618	52,2			1181	99,0	576	48,8		
Day 16	All	1181	99,1	35	3,0			1181	99,0	31	2,6		
Day 17	All	1181	99,1	6	0,5			1181	99,0	10	0,8		
Day 18	All	1181	99,1	3	0,3			1181	99,0	5	0,4		
Day 19	All	1180	99,0	6	0,5			1181	99,0	7	0,6		
Day 20	All	1180	99,0	1	0,1			1181	99,0	1	0,1		
Day 21	All	1180	99,0	2	0,2			1180	98,9	2	0,2		
Day 22	All	1179	98,9	6	0,5			1178	98,7	7	0,6		
Day 23	All	1178	98,8	12	1,0			1177	98,7	5	0,4		
Day 24	All	1178	98,8	11	0,9			1177	98,7	8	0,7		
Day 25	All	1178	98,8	13	1,1			1177	98,7	11	0,9		
Day 26	All	1178	98,8	27	2,3			1177	98,7	23	2,0		
Day 27	All	1178	98,8	51	4,3			1175	98,5	68	5,8		

Day 28	All	1177	98,7	321	27,3			1175	98,5	306	26,0		
Day 29	All	1175	98,6	490	41,7			1173	98,3	470	40,1		
Day 30	All	1174	98,5	1	0,1			1173	98,3	0	0,0		
Day 34	All	1172	98,3	0	0,0			1171	98,2	1	0,1		
Day 120	All	1161	97,4	0	0,0			1152	96,6	1	0,1		
Day 168	All	716	60,1	3	0,4			727	60,9	0	0,0		
Day 169	All	311	26,1	1	0,3			302	25,3	3	1,0		
Day 177	All	19	1,6	0	0,0			24	2,0	1	4,2		

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 19AUG2021

Program: t-eff-mean.sas

Output: t14-3-eff-mean-overall-precol9h.xlsx

POPULATION: mFAS

ENDPOINT: Return to usual activities

MODEL: --

STUDY: R10933-10987-COV-2067

Template Compliance/Mean

		Casirivimab/Imdevimab (N=1192)						Placebo (N=1193)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	mean ²	SD	in study ¹	%	with value ¹	%	mean ²	SD
Visit													
All													
Baseline	All	1188	99,7	792	66,7			1190	99,7	773	65,0		
Day 2	All	1188	99,7	6	0,5			1190	99,7	11	0,9		
Day 3	All	1188	99,7	4	0,3			1190	99,7	3	0,3		
Day 4	All	1187	99,6	6	0,5			1190	99,7	5	0,4		
Day 5	All	1186	99,5	10	0,8			1190	99,7	11	0,9		
Day 6	All	1185	99,4	182	15,4			1189	99,7	182	15,3		
Day 7	All	1184	99,3	639	54,0			1189	99,7	618	52,0		
Day 8	All	1184	99,3	41	3,5			1188	99,6	39	3,3		
Day 9	All	1184	99,3	28	2,4			1188	99,6	17	1,4		
Day 10	All	1184	99,3	14	1,2			1187	99,5	21	1,8		
Day 11	All	1183	99,2	5	0,4			1184	99,2	5	0,4		
Day 12	All	1183	99,2	12	1,0			1184	99,2	6	0,5		
Day 13	All	1183	99,2	13	1,1			1184	99,2	16	1,4		
Day 14	All	1183	99,2	263	22,2			1182	99,1	261	22,1		
Day 15	All	1183	99,2	617	52,2			1181	99,0	578	48,9		
Day 16	All	1181	99,1	35	3,0			1181	99,0	31	2,6		
Day 17	All	1181	99,1	7	0,6			1181	99,0	9	0,8		
Day 18	All	1181	99,1	4	0,3			1181	99,0	5	0,4		
Day 19	All	1180	99,0	7	0,6			1181	99,0	7	0,6		
Day 20	All	1180	99,0	1	0,1			1181	99,0	1	0,1		
Day 21	All	1180	99,0	2	0,2			1180	98,9	2	0,2		
Day 22	All	1179	98,9	5	0,4			1178	98,7	8	0,7		
Day 23	All	1178	98,8	12	1,0			1177	98,7	5	0,4		
Day 24	All	1178	98,8	11	0,9			1177	98,7	10	0,8		
Day 25	All	1178	98,8	13	1,1			1177	98,7	12	1,0		
Day 26	All	1178	98,8	28	2,4			1177	98,7	24	2,0		
Day 27	All	1178	98,8	49	4,2			1175	98,5	62	5,3		

Day 28	All	1177	98,7	320	27,2			1175	98,5	308	26,2		
Day 29	All	1175	98,6	491	41,8			1173	98,3	469	40,0		
Day 30	All	1174	98,5	1	0,1			1173	98,3	0	0,0		
Day 34	All	1172	98,3	0	0,0			1171	98,2	1	0,1		
Day 120	All	1161	97,4	0	0,0			1152	96,6	1	0,1		
Day 168	All	716	60,1	3	0,4			727	60,9	0	0,0		
Day 169	All	311	26,1	1	0,3			302	25,3	3	1,0		
Day 177	All	19	1,6	0	0,0			24	2,0	1	4,2		

¹ in study: number of subjects in study at respective visit; % based on baseline

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

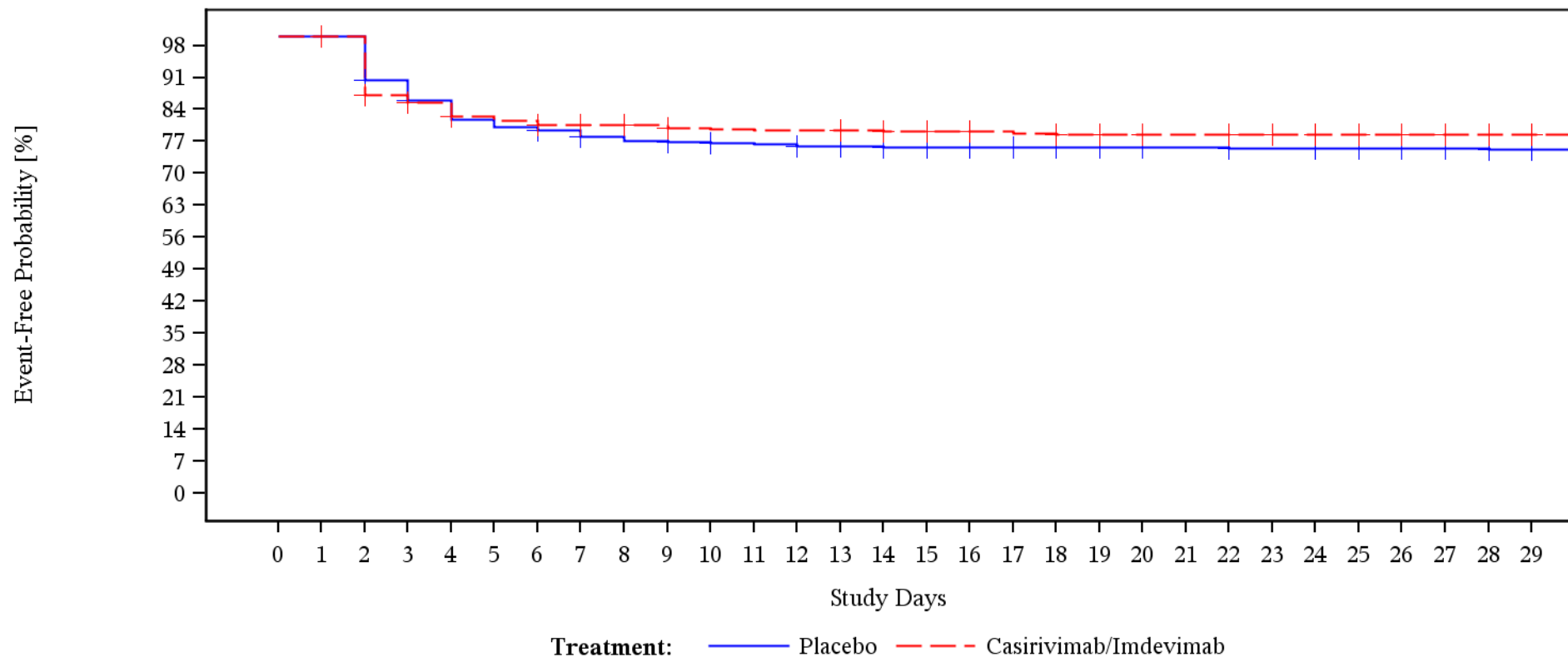
² mean: descriptive statistics - absolute values

Clinical cut-off: 19AUG2021

Program: t-eff-mean.sas

Output: t14-4-eff-mean-overall-precol19a.xlsx

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first deterioration
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	570	513	486	462	453	446	434	429	427	424	423	420	419	416	415	414	413	410	407	405	405	402	402	401	395	387	376	340
Casirivimab/Imdevimab	1192	1192	591	514	503	484	479	470	468	466	460	459	458	458	457	455	453	452	450	447	444	442	442	440	434	432	429	421	414	368

Patients Censored

Placebo	0	623	626	627	627	627	630	634	634	635	636	636	637	638	640	641	642	643	646	649	651	651	652	652	653	659	667	678	713	748
Casirivimab/Imdevimab	0	601	602	603	604	604	608	610	611	613	613	613	613	614	615	616	617	617	619	622	624	624	626	632	634	637	645	652	698	749

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-2-km-plot-ttdet10.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first deterioration

Model: Stratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo						Casirivimab/Imdevimab vs. Placebo										
		Patients		Patients with Event		Censored		Time to event				Patients		Patients with Event		Censored		Time to event				log-rank		Hazard Ratio						
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	1192	100	129	10,822	1063	89,178	177	61	NE	NE	NE	NE	1193	100	143	11,987	1050	88,013	60	7	NE	NE	NE	NE	0,225	0,867	0,684	1,1	Convergence criterion (GCONV=1E-8) satisfied.

Stratification factor = Country.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

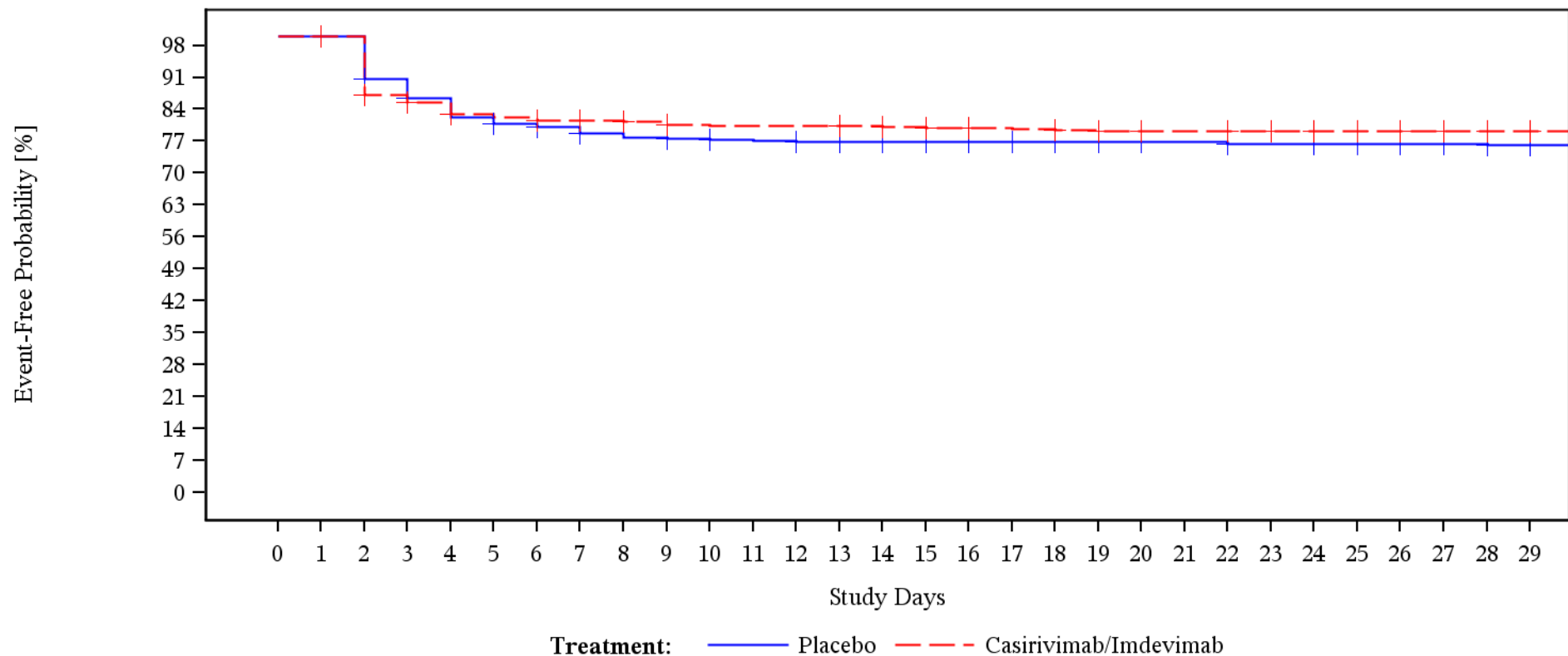
* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas

Output: t13-2-eff-tte-TTDET10

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first deterioration - Sensitivity Analysis
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	570	513	486	462	453	446	435	430	427	424	423	420	419	416	415	414	413	410	407	405	405	402	402	401	395	387	376	340
Casirivimab/Imdevimab	1192	1192	590	513	502	483	479	471	469	467	461	460	459	459	458	456	454	453	451	448	444	442	442	440	434	432	429	421	414	368

Patients Censored

Placebo	0	623	627	630	630	631	634	638	638	639	641	641	643	644	646	647	648	649	652	655	657	657	658	658	659	665	673	684	719	754
Casirivimab/Imdevimab	0	602	603	605	608	608	612	614	615	617	617	617	617	618	619	620	621	621	623	626	628	628	630	636	638	641	649	656	702	753

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-3-km-plot-ttdets10.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first deterioration - Sensitivity Analysis

Model: Stratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo						Casirivimab/Imdevimab vs. Placebo											
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	
All	n/a	1192	100	125	10.487	1067	89.513	177	177	NE	NE	NE	NE	1193	100	137	11.484	1056	88.516	NE	8	NE	NE	NE	NE	0,2767	0,878	0,689	1,119	Convergence criterion (GCONV=1E-8) satisfied.	

Stratification factor = Country.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

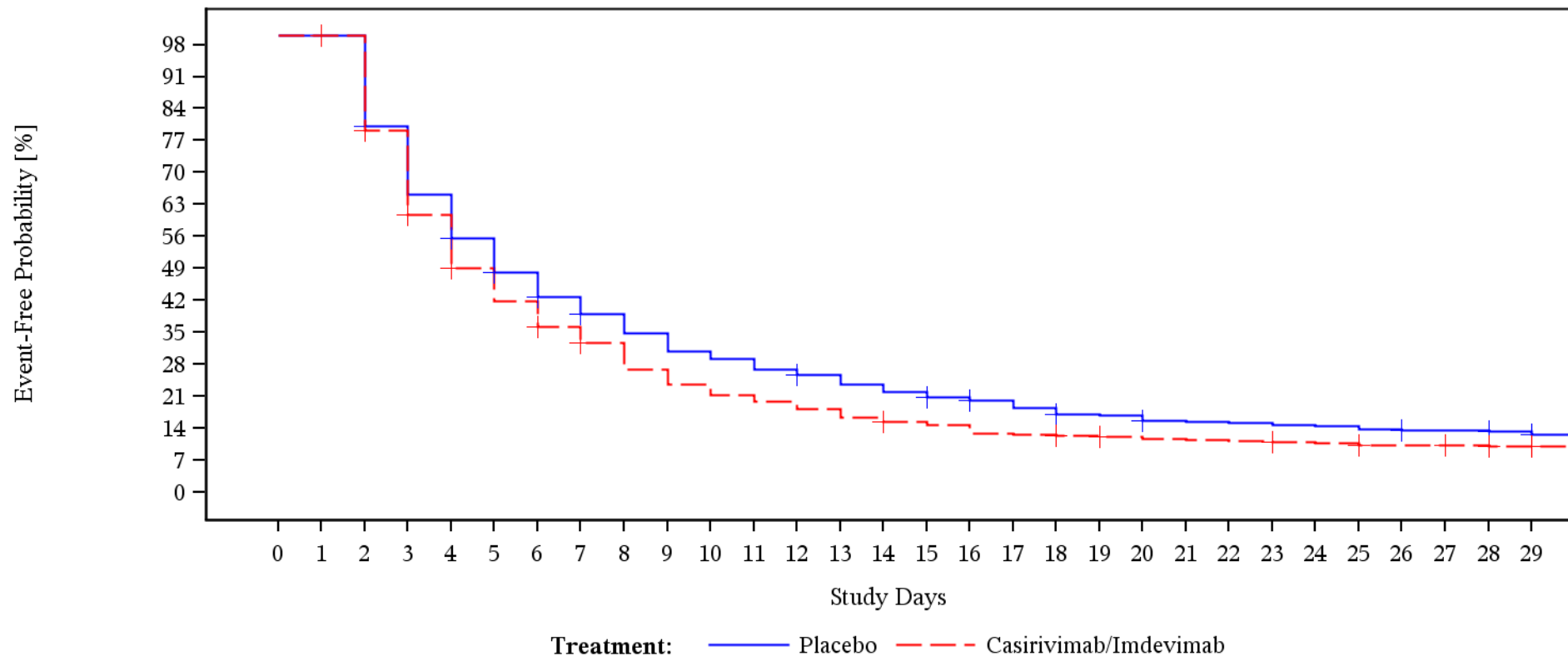
* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas

Output: t13-3-eff-tte-TTDETS10

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first improvement
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	570	453	368	312	270	238	216	192	171	161	148	141	130	120	113	109	99	91	90	83	81	80	78	76	73	69	69	67
Casirivimab/Imdevimab	1192	1192	590	466	356	285	243	210	188	154	136	122	114	105	94	86	83	72	71	68	66	64	62	61	59	58	54	54	53	47

Patients Censored

Placebo	0	623	627	627	629	630	631	633	633	633	633	633	634	634	634	635	636	636	637	637	638	638	638	638	638	638	640	640	641	642	
Casirivimab/Imdevimab	0	602	604	605	607	607	608	610	610	610	610	610	610	610	610	612	612	612	612	613	614	614	614	614	615	615	616	616	617	622	628

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-4-km-plot-timp10.pdf

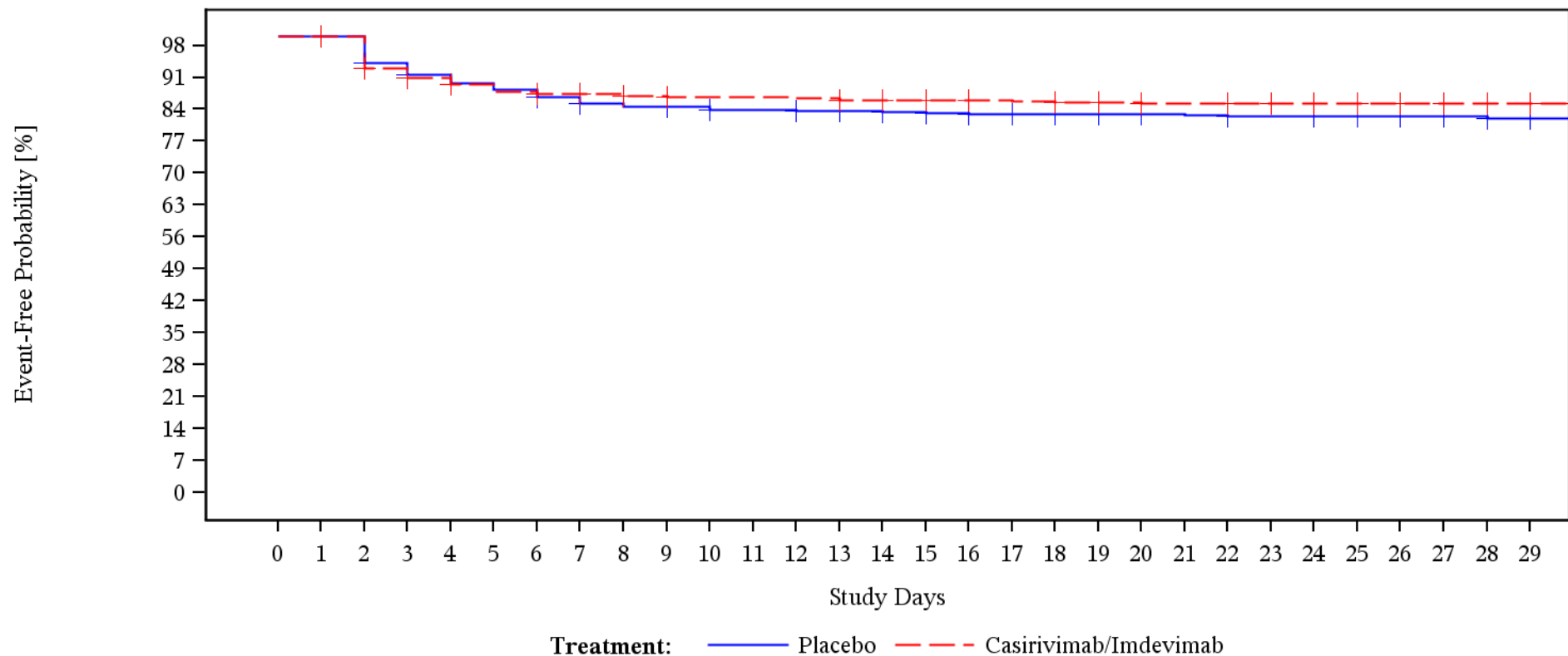
POPULATION: Modified Full Analysis Set
ENDPOINT: EQ-5D-5L VAS/ MID=10: Time to first improvement
Model: Stratified analysis
STUDY: R10933-10987-COV-2067
Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab											Placebo						Casirivimab/Imdevimab vs. Placebo											
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event				log-rank		Hazard Ratio					
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	1192	100	532	44,631	660	55,369	3	NE	NE	4	4	5	1193	100	513	43,001	680	56,999	3	NE	NE	5	5	6	0,027	1,135	1,005	1,282	Convergence criterion (GCONV=1E-8) satisfied.

Stratification factor = Country.
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
 * indicates convergence problem. Result is uninterpretable
 Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas
 Output: t13-4-eff-tte-TTIMP10

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	570	534	518	507	499	487	476	472	469	465	463	462	458	456	452	451	448	445	443	442	440	440	439	433	425	414	372	
Casirivimab/Imdevimab	1192	1192	591	547	534	525	516	509	506	503	500	499	499	498	495	494	493	491	490	487	484	481	481	478	472	470	467	457	450	398

Patients Censored

Placebo	0	623	626	627	627	627	630	634	634	636	637	637	638	639	641	642	644	645	648	651	653	653	654	654	655	661	669	680	720	761
Casirivimab/Imdevimab	0	601	603	604	605	605	609	611	612	614	614	614	614	615	616	617	618	618	620	623	625	625	628	634	636	639	649	656	708	761

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-tt det15.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					
Name	Level	Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank p-value	Hazard Ratio				Interaction Test p-value (likelihood ratio)
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	
All	n/a	1192	100	87	7,299	1105	92,701	NE	NE	NE	NE	NE	NE	1193	100	105	8,801	1088	91,199	NE	NE	NE	NE	NE	NE	0,1101	0,797	0,6	1,059	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	579	48,574	34	5,872	545	94,128	NE	NE	NE	NE	NE	NE	580	48,617	51	8,793	529	91,207	NE	NE	NE	NE	NE	NE	0,0473	0,651	0,422	1,004	Convergence criterion (GCONV=1E-8) satisfied.	0,2181
	Female	613	51,426	53	8,646	560	91,354	NE	NE	NE	NE	NE	NE	613	51,383	54	8,809	559	91,191	NE	165	NE	NE	NE	NE	0,7054	0,931	0,637	1,36	Convergence criterion (GCONV=1E-8) satisfied.	
Age	18-64	1043	87,5	73	6,999	970	93,001	NE	NE	NE	NE	NE	NE	1051	88,097	84	7,992	967	92,008	NE	NE	NE	NE	NE	NE	0,3053	0,851	0,622	1,165	Convergence criterion (GCONV=1E-8) satisfied.	0,1932
	65-74	100	8,389	7	7	93	93	NE	6	NE	NE	NE	NE	108	9,053	14	12,963	94	87,037	12	3	NE	NE	NE	NE	0,0975	0,478	0,193	1,185	Convergence criterion (GCONV=1E-8) satisfied.	
	>=75	49	4,111	7	14,286	42	85,714	2	2	NE	NE	2	NE	34	2,85	7	20,588	27	79,412	2	2	6	5	2	28	0,047	0,393	0,137	1,127	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline viral load categories	<=10^5 copies/mL	260	21,812	14	5,385	246	94,615	NE	NE	NE	NE	NE	NE	242	20,285	14	5,785	228	94,215	NE	NE	NE	NE	NE	NE	0,988	0,994	0,474	2,086	Convergence criterion (GCONV=1E-8) satisfied.	0,6064
	>10^5 copies/mL - <=10^6 copies/mL	158	13,255	11	6,962	147	93,038	NE	NE	NE	NE	NE	NE	183	15,339	12	6,557	171	93,443	NE	6	NE	NE	NE	NE	0,4808	0,748	0,33	1,696	Convergence criterion (GCONV=1E-8) satisfied.	
	>10^6 copies/mL - <=10^7 copies/mL	183	15,352	13	7,104	170	92,896	NE	NE	NE	NE	NE	NE	205	17,184	29	14,146	176	85,854	60	7	NE	NE	NE	NE	0,0695	0,556	0,289	1,07	Convergence criterion (GCONV=1E-8) satisfied.	
	>10^7 copies/mL	590	49,497	49	8,305	541	91,695	NE	NE	NE	NE	NE	NE	561	47,024	50	8,913	511	91,087	NE	NE	NE	NE	NE	NE	0,5651	0,893	0,602	1,324	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio				Interaction Test		
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)			
	Unknown	1	0,084	0	0	1	100	NE	NE	NE	NE	NE	NE	2	0,168	0	0	2	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Country	USA	1116	93,624	87	7,796	1029	92,204	NE	NE	NE	NE	NE	NE	1112	93,21	105	9,442	1007	90,558	NE	NE	NE	NE	NE	NE	NE	0,1101	0,797	0,6	1,059	Convergence criterion (GCONV=1E-8) satisfied.			
	MEX	76	6,376	0	0	76	100	NE	NE	NE	NE	NE	NE	81	6,79	0	0	81	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	979	82,131	75	7,661	904	92,339	NE	NE	NE	NE	NE	NE	984	82,481	88	8,943	896	91,057	NE	NE	NE	NE	NE	NE	NE	0,1703	0,81	0,595	1,102	Convergence criterion (GCONV=1E-8) satisfied.	0,7745		
	Black or African American	55	4,614	4	7,273	51	92,727	NE	3	NE	NE	NE	NE	51	4,275	8	15,686	43	84,314	12	4	NE	NE	60	NE	0,2675	0,516	0,155	1,713	Convergence criterion (GCONV=1E-8) satisfied.				
	Asian/American Indian Alaska Native/Native Hawaiian or other Pacific Islander	85	7,131	5	5,882	80	94,118	NE	2	NE	NE	NE	NE	70	5,868	5	7,143	65	92,857	21	2	NE	NE	21	NE	0,7815	0,842	0,244	2,91	Convergence criterion (GCONV=1E-8) satisfied.				
	Unknown/Not Reported	73	6,124	3	4,11	70	95,89	NE	2	NE	NE	NE	NE	88	7,376	4	4,545	84	95,455	NE	4	NE	NE	NE	NE	0,9294	0,935	0,209	4,178	Convergence criterion (GCONV=1E-8) satisfied.				
Baseline serostatus	Negative	798	66,946	59	7,393	739	92,607	NE	NE	NE	NE	NE	NE	813	68,148	77	9,471	736	90,529	NE	NE	NE	NE	NE	NE	NE	0,1467	0,782	0,557	1,097	Convergence criterion (GCONV=1E-8) satisfied.	0,8045		
	Positive	311	26,091	19	6,109	292	93,891	NE	NE	NE	NE	NE	NE	284	23,806	23	8,099	261	91,901	NE	21	NE	NE	NE	NE	NE	0,2702	0,715	0,389	1,312	Convergence criterion (GCONV=1E-8) satisfied.			
	Other	83	6,963	9	10,843	74	89,157	NE	6	NE	NE	NE	NE	96	8,047	5	5,208	91	94,792	NE	NE	NE	NE	NE	NE	NE	0,5039	1,44	0,483	4,297	Convergence criterion (GCONV=1E-8) satisfied.			

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

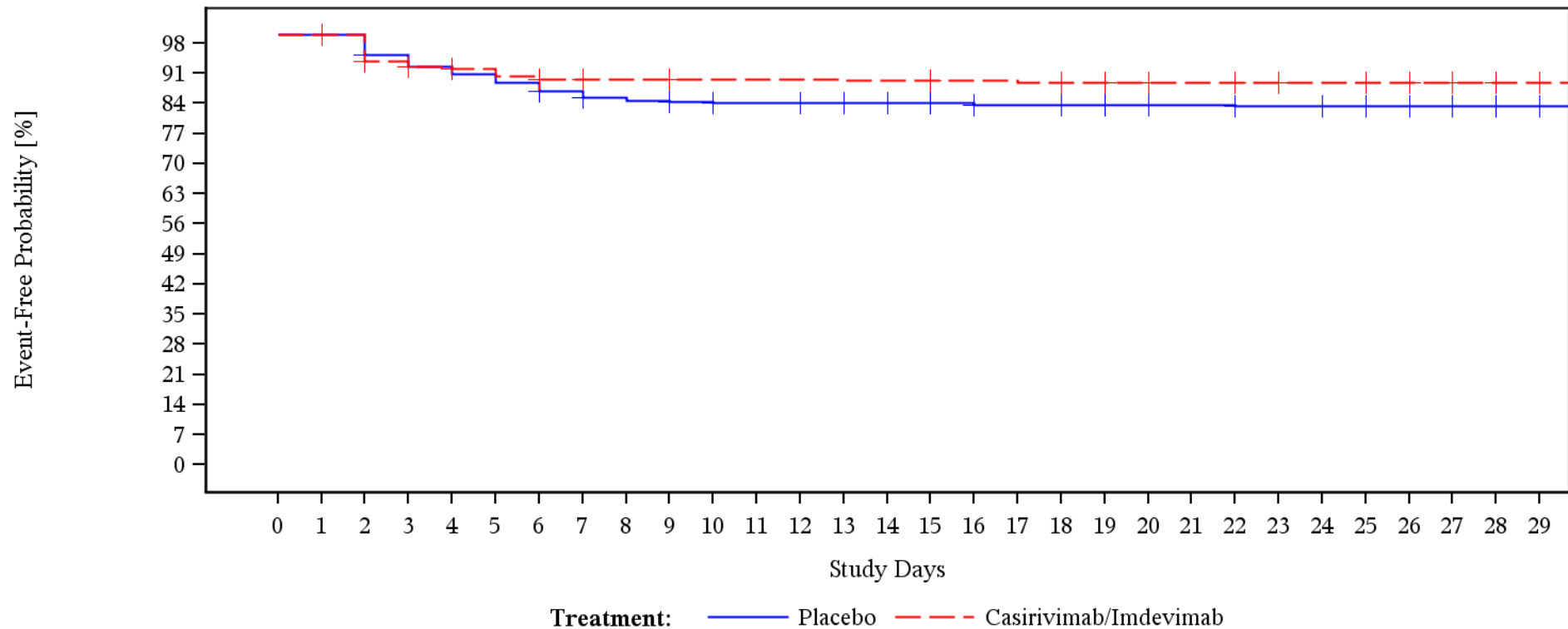
		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo									
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

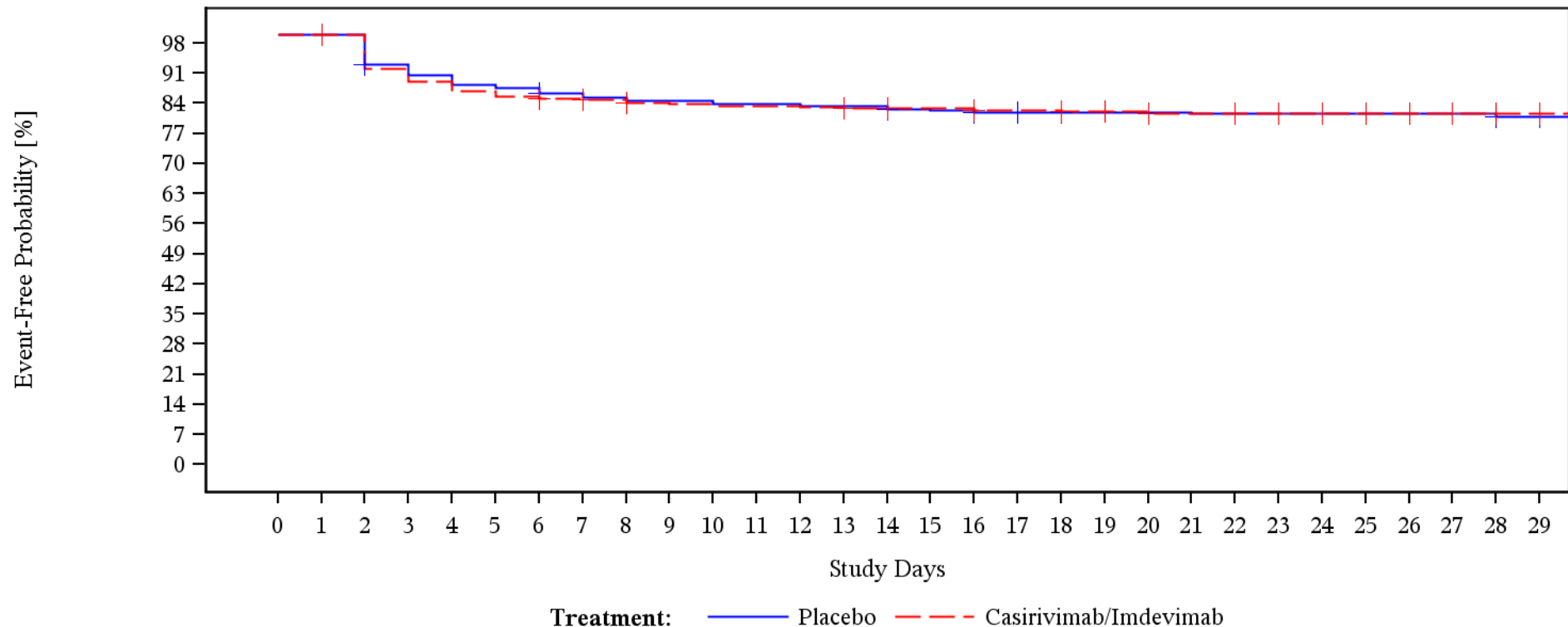
Placebo	580	580	296	281	272	267	261	253	245	243	240	238	237	236	235	234	232	232	231	228	226	226	224	224	223	219	214	207	184
Casirivimab/Imdevimab	579	579	300	279	275	272	267	263	262	262	260	260	260	259	259	258	258	257	256	255	254	254	252	249	249	247	241	237	206

Patients Censored

Placebo	0	284	285	286	286	286	288	292	292	294	295	295	296	297	298	299	300	300	301	304	306	306	307	307	308	312	317	324	347	366
Casirivimab/Imdevimab	0	279	281	282	283	283	285	286	286	288	288	288	288	288	288	289	289	289	290	291	292	292	294	297	297	299	305	309	340	366

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

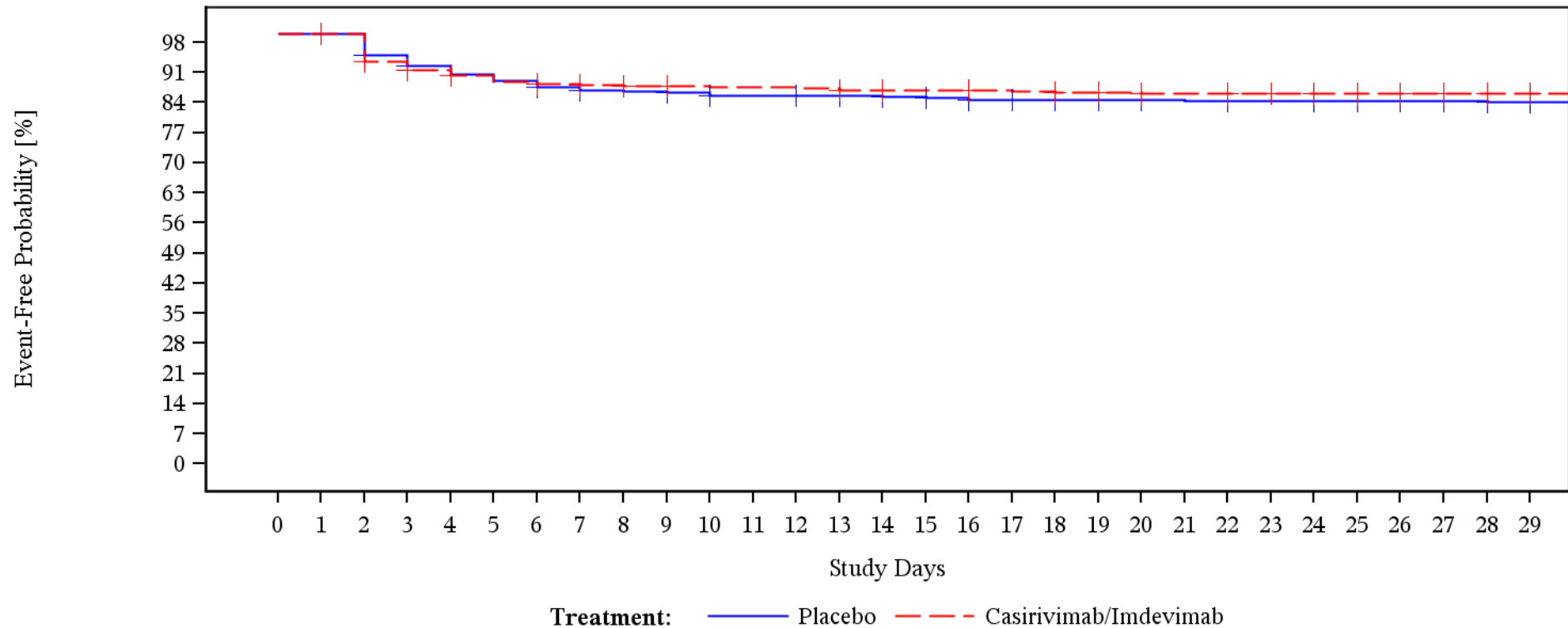
Placebo	613	613	274	253	246	240	238	234	231	229	229	227	227	226	226	223	222	220	219	217	217	217	216	216	216	216	214	211	207	188
Casirivimab/Imdevimab	613	613	291	268	259	253	249	246	244	241	240	239	239	238	236	235	235	233	233	231	229	227	227	226	223	221	220	216	213	192

Patients Censored

Placebo	0	339	341	341	341	341	342	342	342	342	342	342	342	342	343	343	344	345	347	347	347	347	347	347	347	349	352	356	373	395
Casirivimab/Imdevimab	0	322	322	322	322	322	324	325	326	326	326	326	326	327	328	328	329	329	330	332	333	333	334	337	339	340	344	347	368	395

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

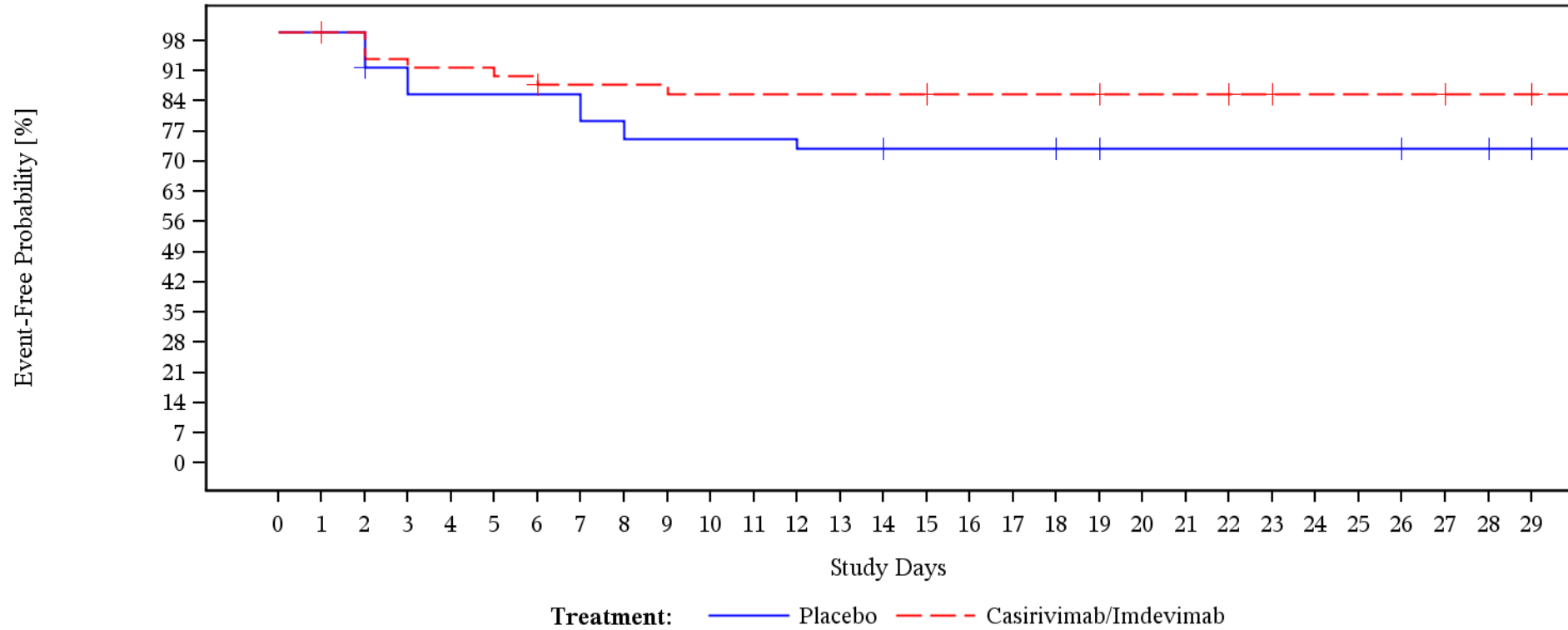
Placebo	1051	1051	513	485	472	462	454	443	436	434	431	427	427	426	425	422	420	416	415	413	411	409	408	406	406	405	399	392	381	341
Casirivimab/Imdevimab	1043	1043	524	488	477	469	461	456	453	450	448	447	447	446	443	442	442	440	439	437	435	432	432	430	426	424	421	411	405	356

Patients Censored

Placebo	0	538	540	541	541	541	544	548	548	550	551	551	552	553	554	555	557	558	560	562	564	564	565	565	566	572	579	590	629	666
Casirivimab/Imdevimab	0	519	521	522	523	523	526	528	529	531	531	531	531	532	533	533	534	534	535	537	539	539	541	545	547	550	560	566	615	662

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

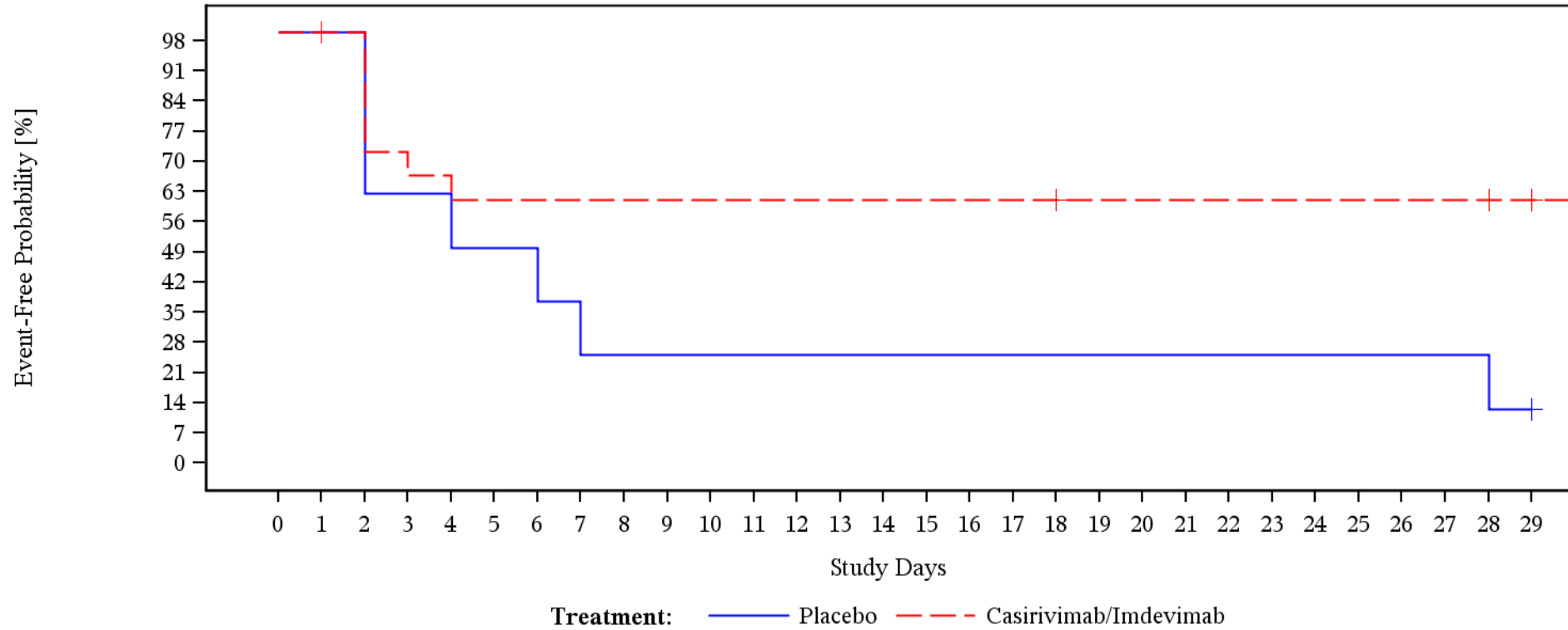
Placebo	108	108	49	44	41	41	41	41	38	36	36	36	36	35	35	34	34	34	34	33	32	32	32	32	32	32	31	31	30
Casirivimab/Imdevimab	100	100	49	46	45	45	44	42	42	42	41	41	41	41	41	41	40	40	40	40	39	39	39	38	36	36	36	35	35

Patients Censored

Placebo	0	59	60	60	60	60	60	60	60	60	60	60	60	60	61	61	61	61	62	63	63	63	63	63	63	63	64	64	65	68
Casirivimab/Imdevimab	0	51	51	51	51	51	52	52	52	52	52	52	52	52	52	53	53	53	53	54	54	54	55	57	57	57	57	58	58	62

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

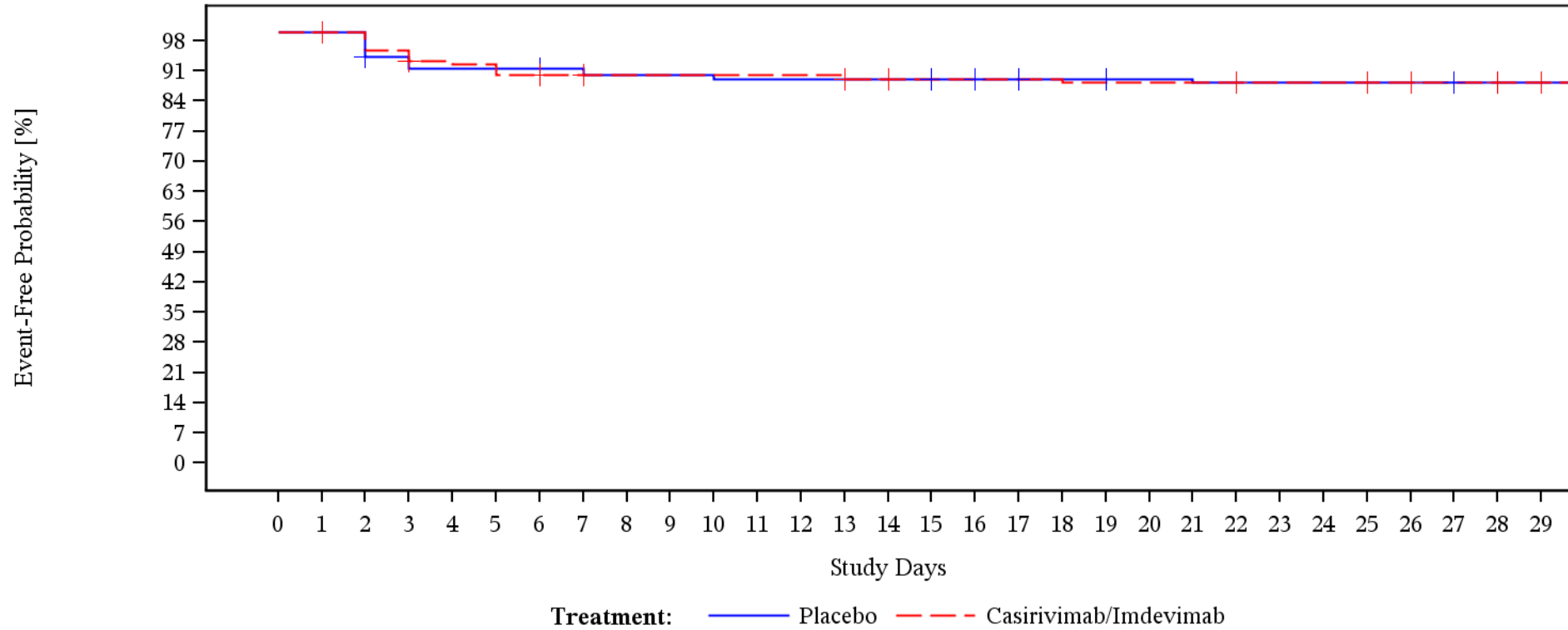
Placebo	34	34	8	5	5	4	4	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
Casirivimab/Imdevimab	49	49	18	13	12	11	11	11	11	11	11	11	11	11	11	11	11	10	10	10	10	10	10	10	7

Patients Censored

Placebo	0	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	27		
Casirivimab/Imdevimab	0	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31	32	32	32	32	32	32	32	32	35	37

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

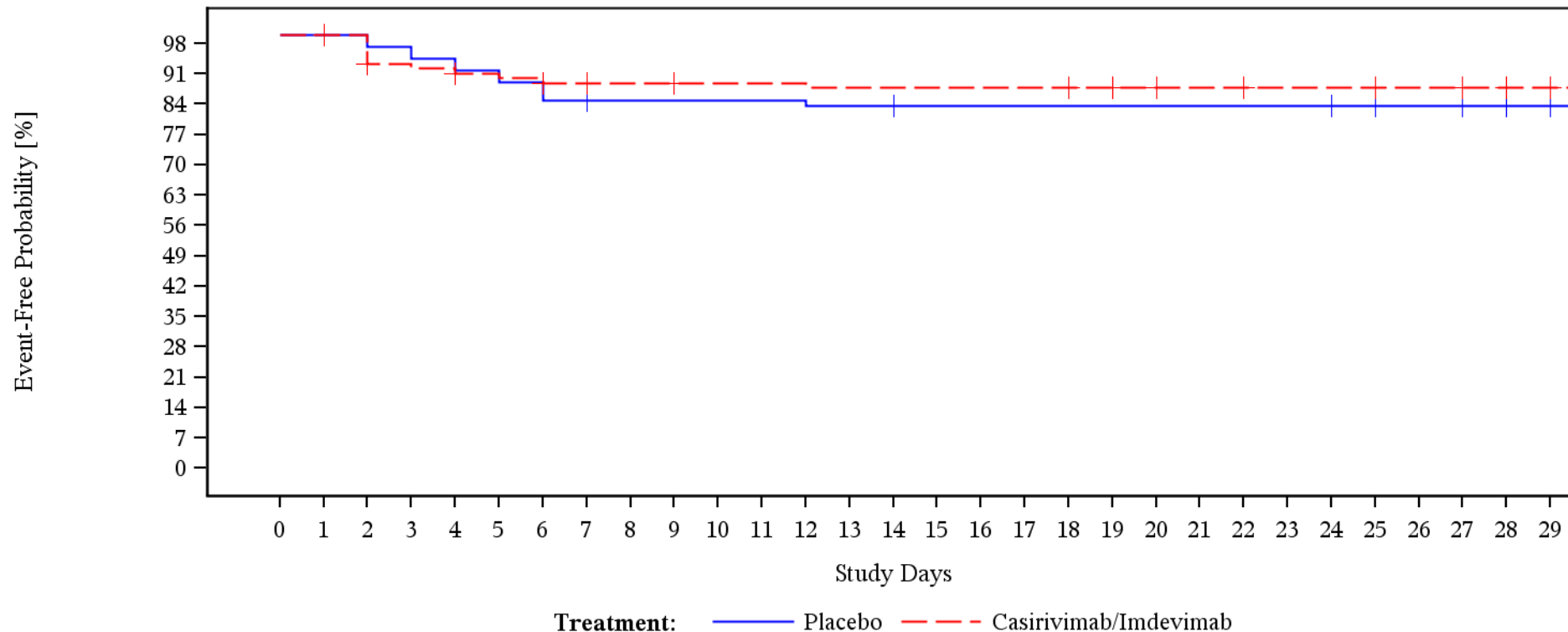
Placebo	242	242	120	112	109	109	109	108	106	106	106	105	105	105	105	105	104	103	102	102	101	101	100	99	99	99	98	95	91	79
Casirivimab/Imdevimab	260	260	120	115	111	110	107	106	105	105	105	105	105	105	103	102	102	102	102	101	101	101	101	100	100	100	99	95	95	81

Patients Censored

Placebo	0	122	123	123	123	123	124	124	124	124	124	124	124	124	124	125	126	127	127	128	128	128	129	129	129	130	133	137	149	163
Casirivimab/Imdevimab	0	140	140	141	141	141	142	143	143	143	143	143	143	144	145	145	145	145	145	145	145	145	146	146	146	147	151	151	165	180

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

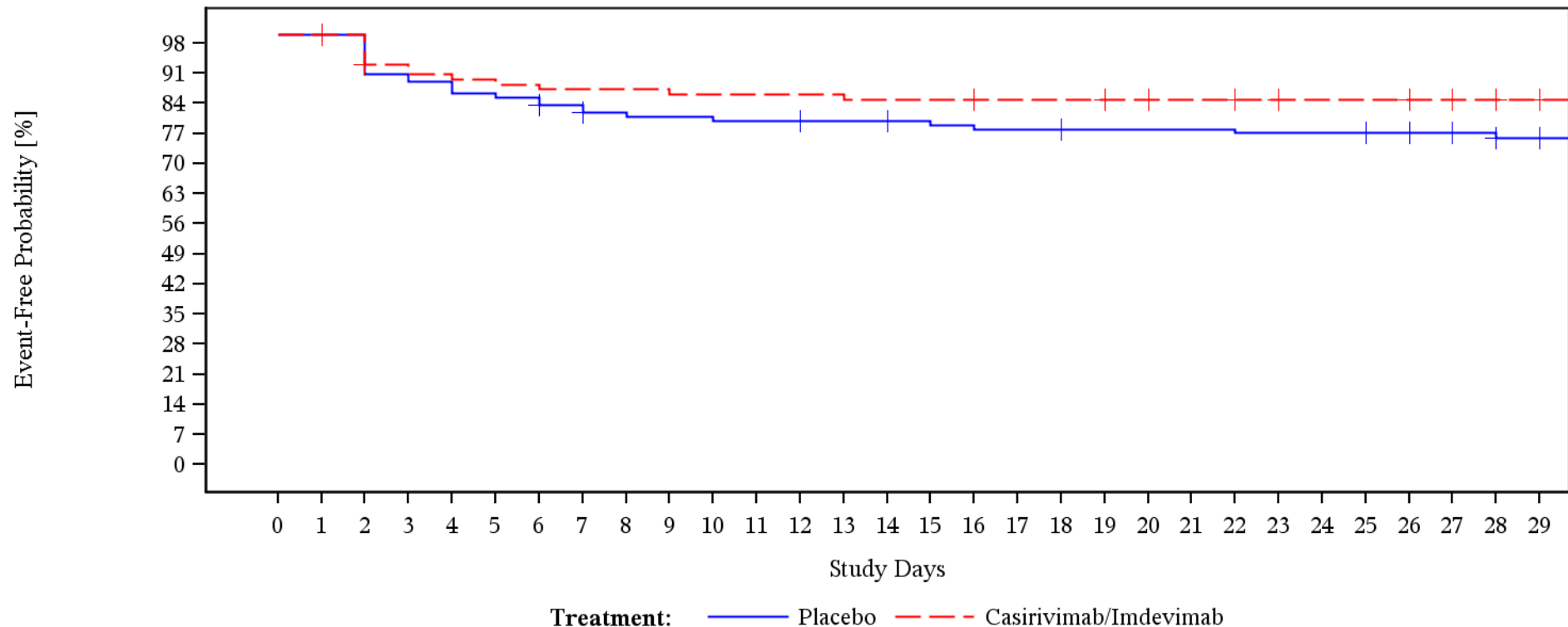
Placebo	183	183	73	71	69	67	65	62	61	61	61	61	61	60	60	59	59	59	59	59	59	59	59	59	58	57	57	55	48	
Casirivimab/Imdevimab	158	158	91	84	83	81	80	78	77	77	76	76	76	75	75	75	75	75	75	74	73	72	72	71	71	71	69	69	67	60

Patients Censored

Placebo	0	110	110	110	110	110	110	111	111	111	111	111	111	111	112	112	112	112	112	112	112	112	112	112	113	114	114	116	123	128	
Casirivimab/Imdevimab	0	67	68	68	69	69	70	71	71	72	72	72	72	72	72	72	72	72	72	73	74	75	75	76	76	76	78	78	80	87	97

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

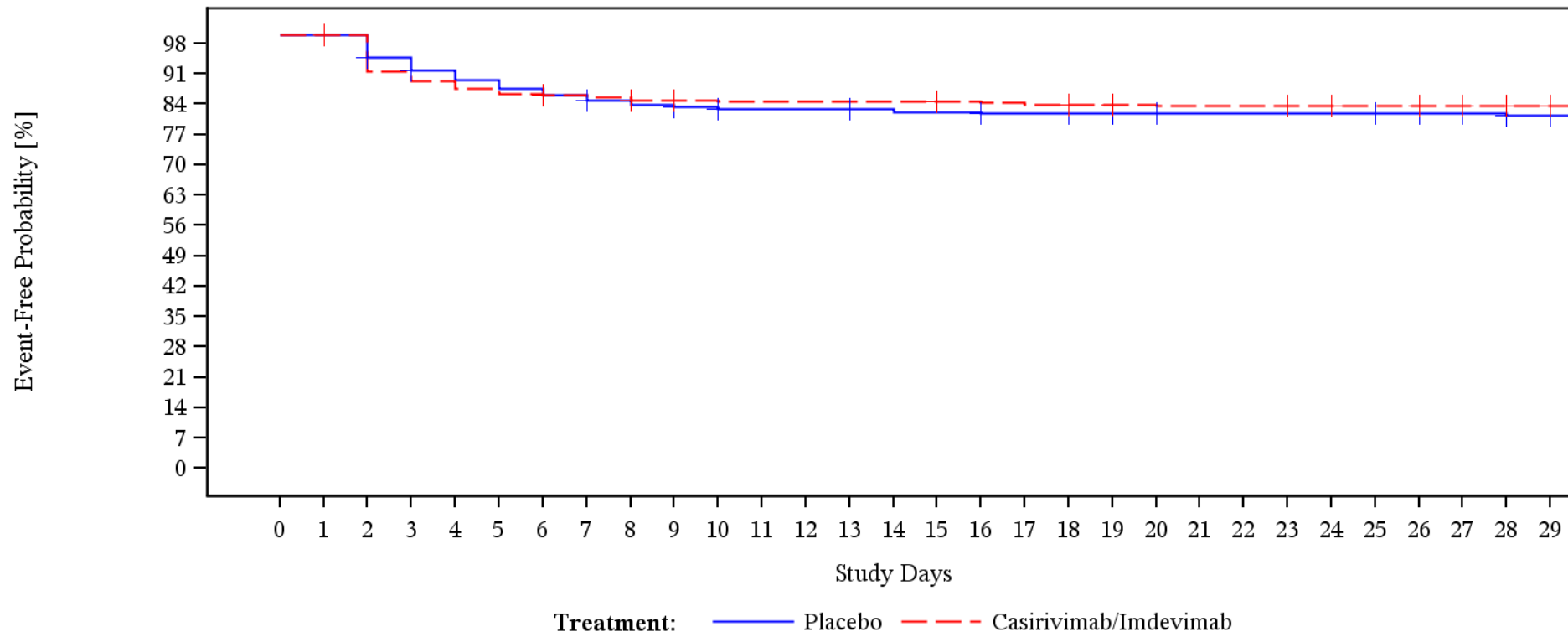
Placebo	205	205	110	100	98	95	94	91	88	87	87	86	86	85	85	84	83	82	82	80	80	80	80	79	79	79	78	77	74	68
Casirivimab/Imdevimab	183	183	87	80	78	77	76	75	75	75	74	74	74	74	73	73	73	72	72	72	71	70	70	69	68	68	68	67	65	60

Patients Censored

Placebo	0	95	95	95	95	95	96	97	97	97	97	97	98	98	99	99	99	99	99	101	101	101	101	101	101	101	102	103	106	111	117			
Casirivimab/Imdevimab	0	96	97	97	97	97	97	97	97	97	97	97	97	97	97	97	97	97	97	97	98	98	98	99	100	100	101	102	102	102	103	105	110	116

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

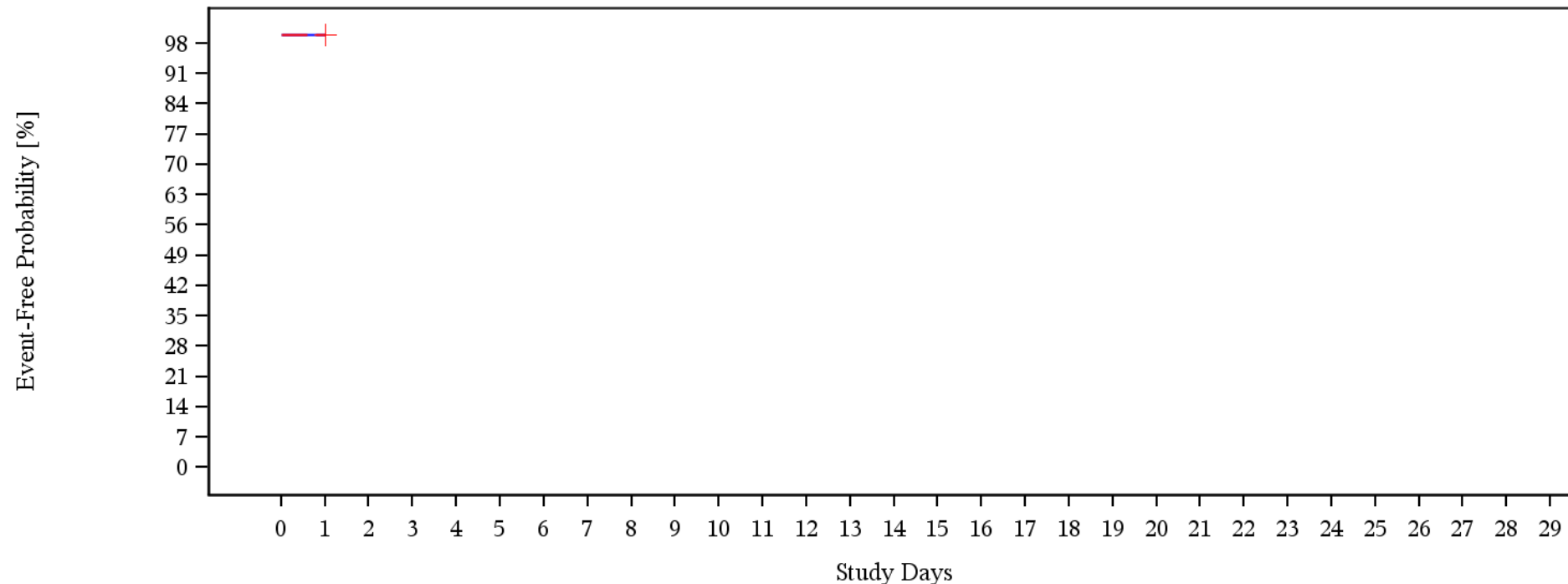
Placebo	561	561	267	251	242	236	231	226	221	218	215	213	213	212	210	210	208	208	207	205	203	203	203	203	200	196	194	177	
Casirivimab/Imdevimab	590	590	293	268	262	257	253	250	249	246	245	244	244	244	244	243	242	241	240	239	238	238	238	233	231	231	226	223	197

Patients Censored

Placebo	0	294	296	297	297	297	298	300	300	302	303	303	303	304	304	304	305	305	306	308	310	310	310	310	310	313	317	319	335	351
Casirivimab/Imdevimab	0	297	297	297	297	297	299	299	300	301	301	301	301	301	301	302	302	302	303	304	304	304	304	309	311	311	316	319	345	367

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=Unknown



Treatment: — Placebo - - Casirivimab/Imdevimab

Patients At Risk

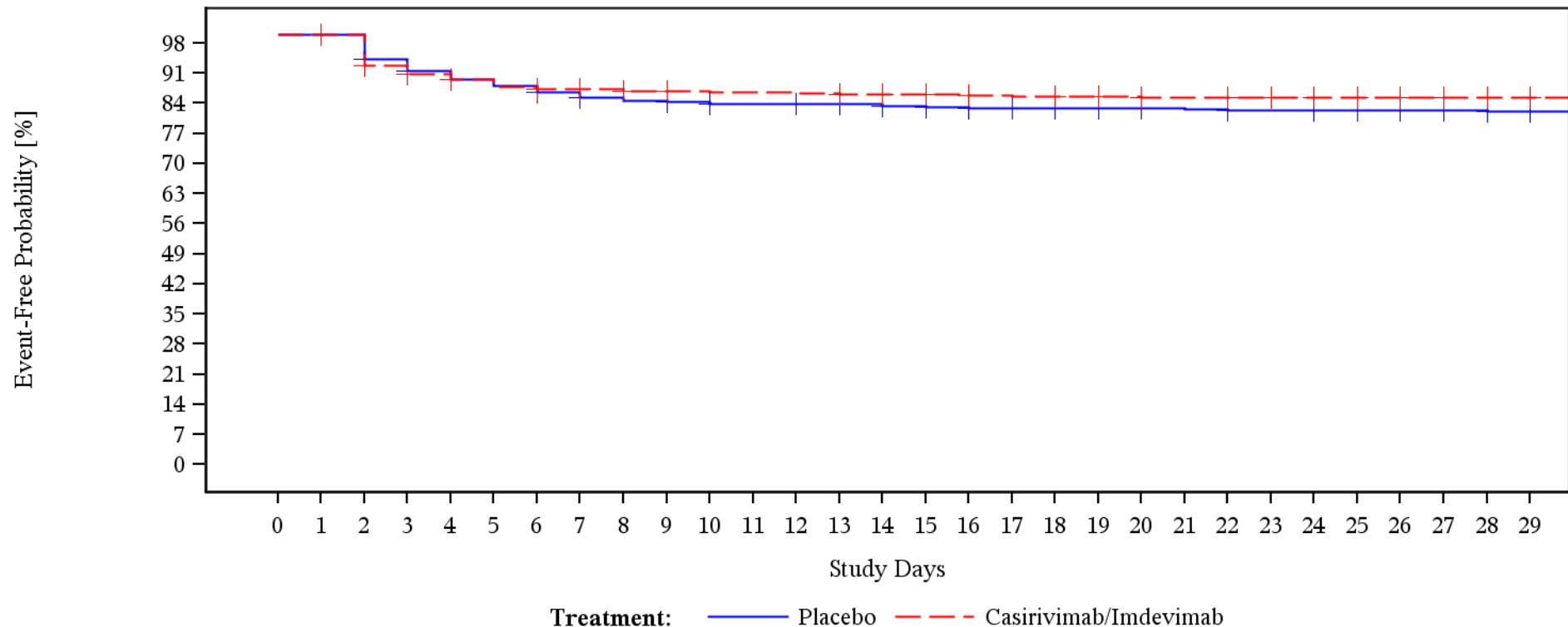
Placebo	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Casirivimab/Imdevimab	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

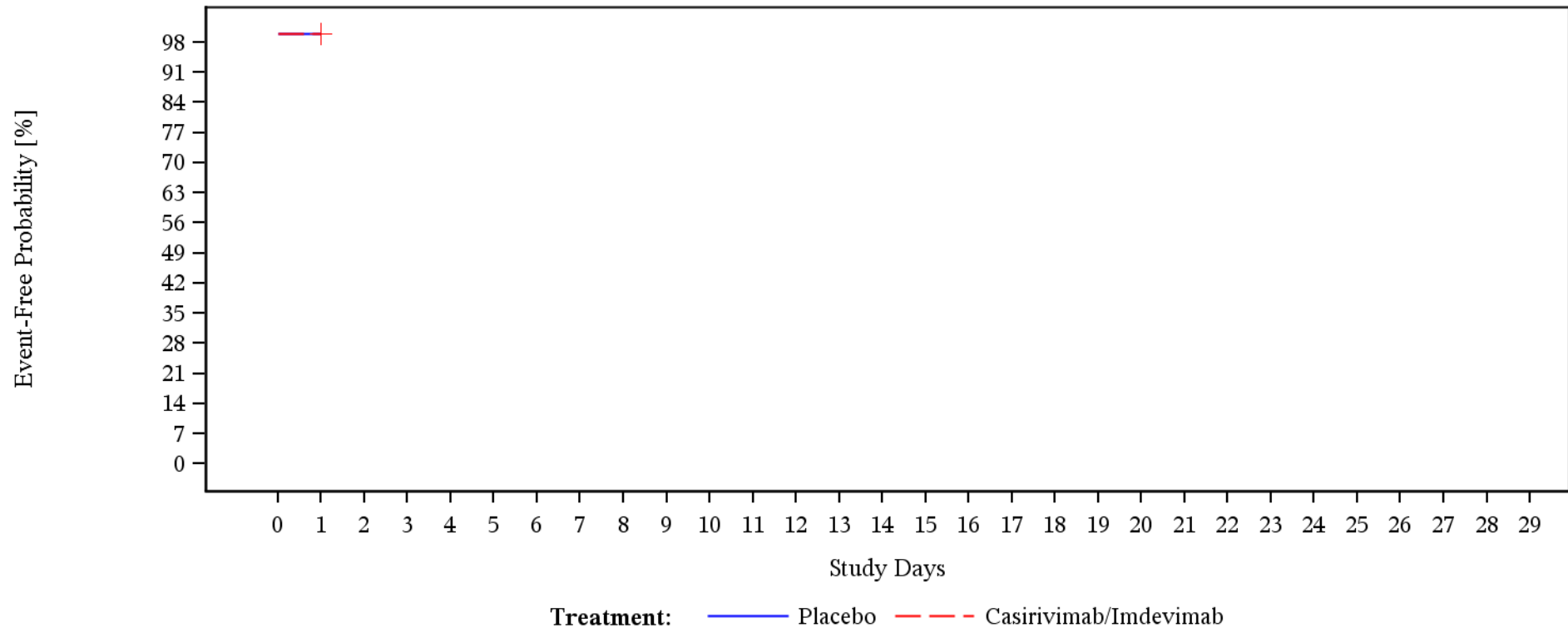
Placebo	1112	1112	570	534	518	507	499	487	476	472	469	465	463	462	458	456	452	451	448	445	443	442	440	440	439	433	425	414	372	
Casirivimab/Imdevimab	1116	1116	591	547	534	525	516	509	506	503	500	499	499	498	495	494	493	491	490	487	484	481	481	478	472	470	467	457	450	398

Patients Censored

Placebo	0	542	545	546	546	546	549	553	553	555	556	556	557	558	560	561	563	564	567	570	572	572	573	573	574	580	588	599	639	680
Casirivimab/Imdevimab	0	525	527	528	529	529	533	535	536	538	538	538	538	539	540	541	542	542	544	547	549	549	552	558	560	563	573	580	632	685

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Country=MEX



Patients At Risk

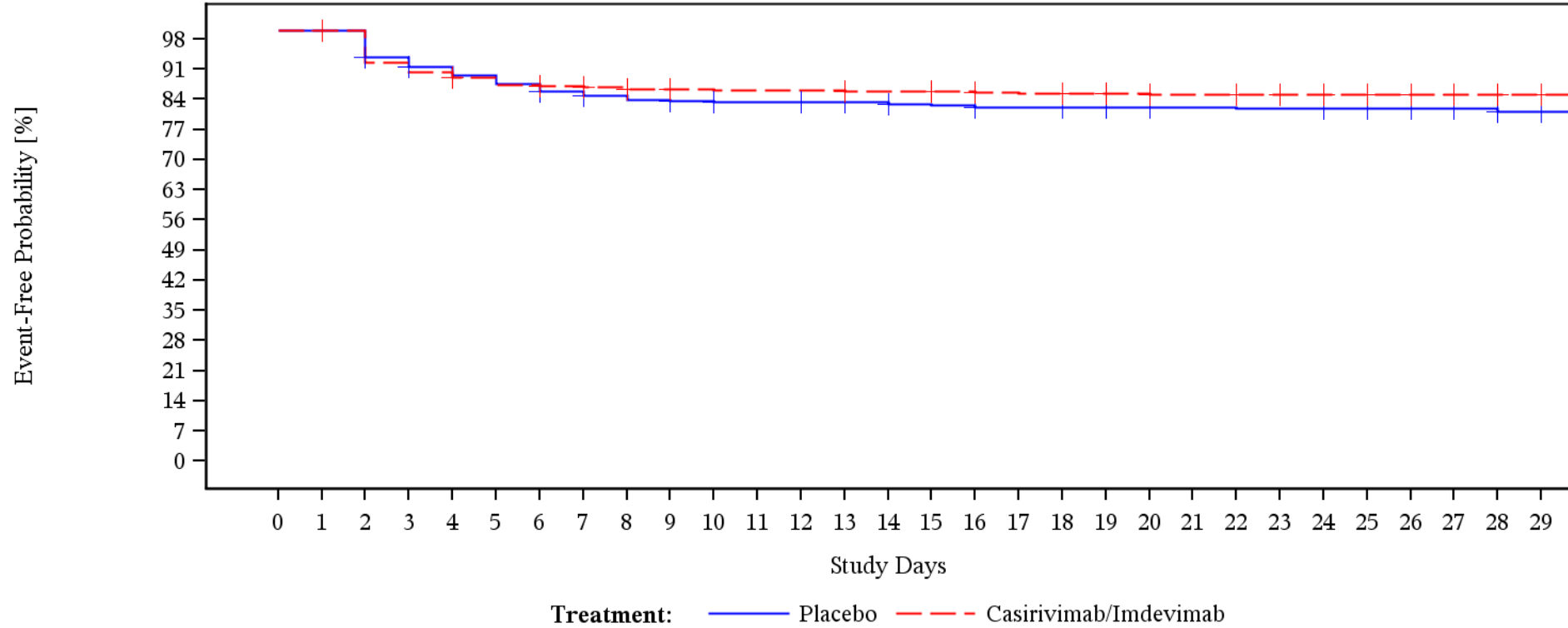
Placebo	81	81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	76	76	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81
Casirivimab/Imdevimab	0	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

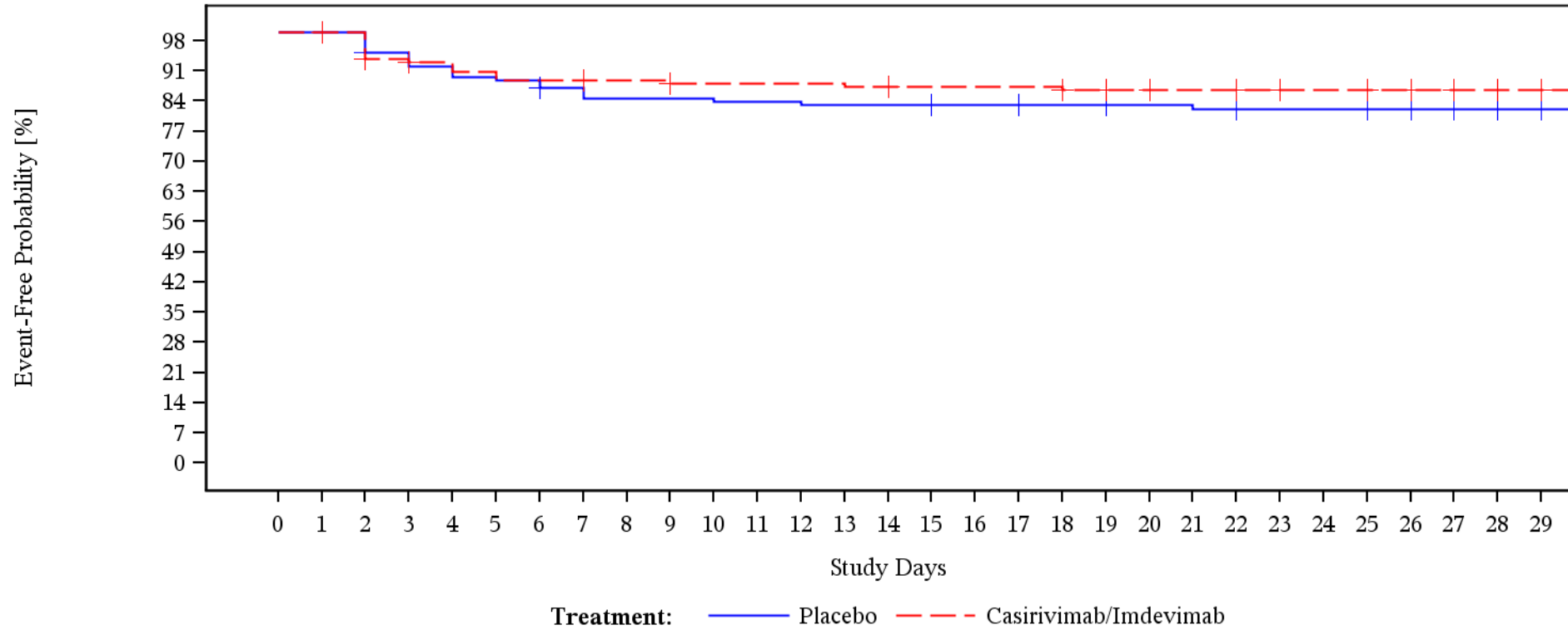
Placebo	813	813	400	373	363	355	348	339	331	327	325	323	323	322	321	317	316	312	312	310	308	306	306	305	305	304	300	296	288	263
Casirivimab/Imdevimab	798	798	390	361	352	346	340	335	333	330	329	328	328	328	326	326	325	323	322	321	319	317	317	316	311	309	308	301	296	259

Patients Censored

Placebo	0	413	415	416	416	416	418	422	422	423	424	424	425	426	428	428	430	430	432	434	436	436	436	436	437	441	445	453	476	501
Casirivimab/Imdevimab	0	408	408	408	409	409	413	414	415	416	416	416	416	417	417	418	419	419	420	422	423	423	424	429	431	432	439	444	481	515

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

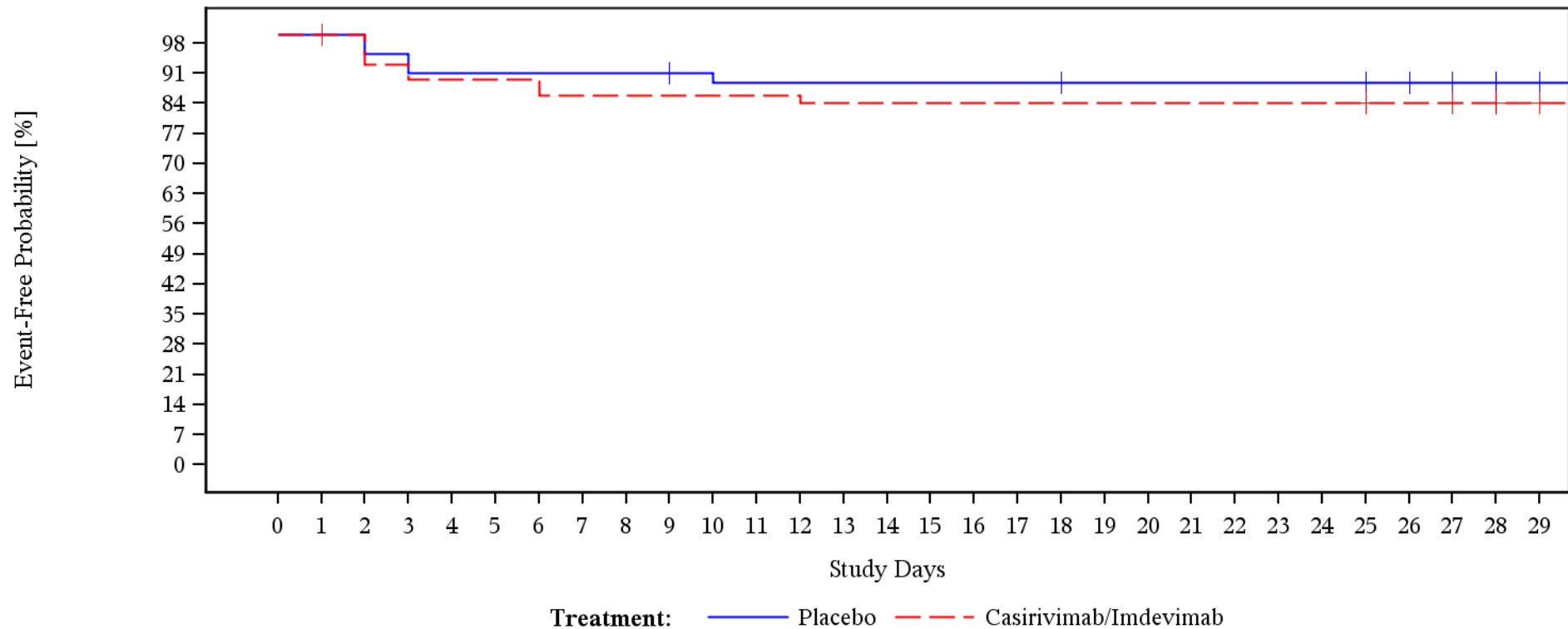
Placebo	284	284	125	118	114	111	110	107	104	104	104	103	103	102	102	102	101	101	100	100	99	99	98	97	97	97	96	93	91	81
Casirivimab/Imdevimab	311	311	144	133	131	128	125	125	124	124	122	122	122	122	121	120	120	120	120	118	117	116	116	114	113	113	112	109	108	99

Patients Censored

Placebo	0	159	160	160	160	160	161	161	161	161	161	161	161	161	162	162	163	163	164	164	164	164	165	165	165	166	169	171	181	193
Casirivimab/Imdevimab	0	167	169	170	170	170	170	171	171	172	172	172	172	172	173	173	173	173	174	175	176	176	178	179	179	180	183	184	193	208

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

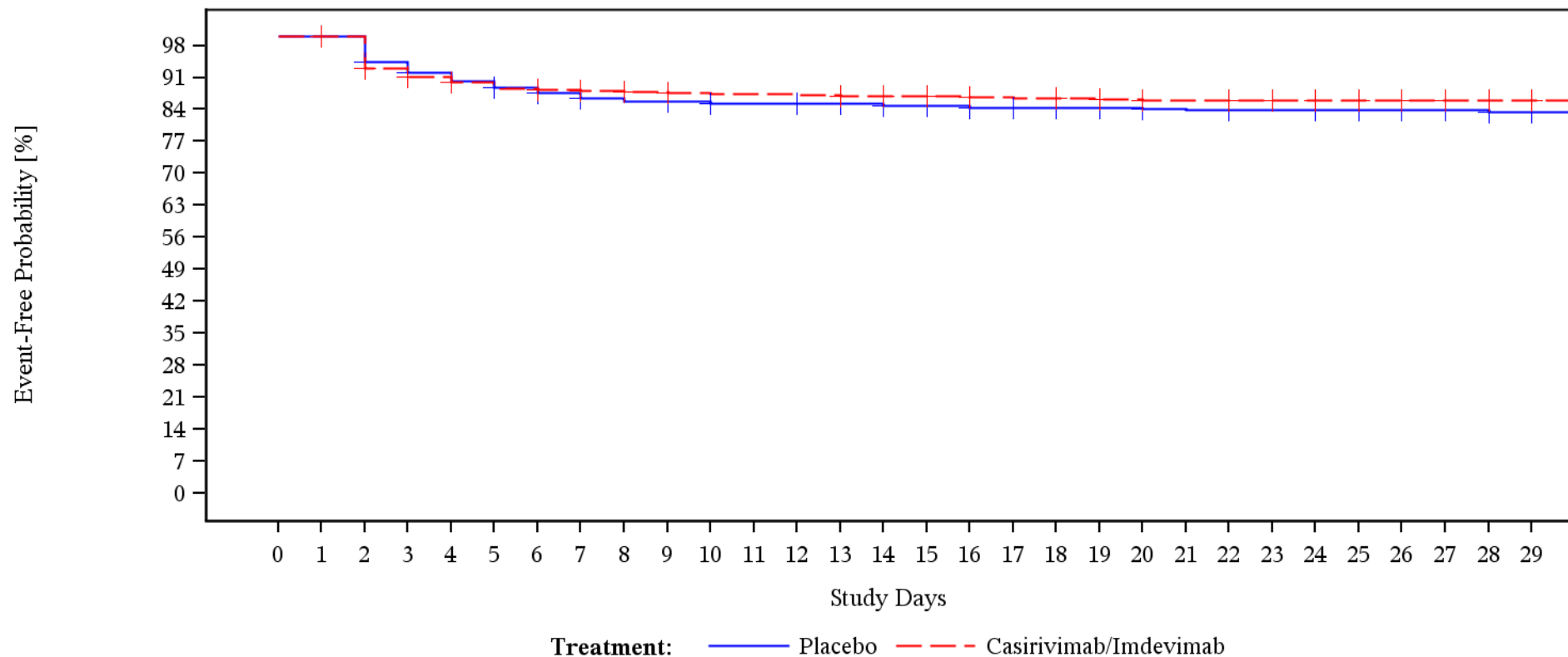
Placebo	96	96	45	43	41	41	41	41	41	41	40	39	39	39	39	39	39	39	38	38	38	38	38	38	37	36	35	28
Casirivimab/Imdevimab	83	83	57	53	51	51	51	49	49	49	49	49	48	48	48	48	48	48	48	48	48	48	48	48	47	47	46	40

Patients Censored

Placebo	0	51	51	51	51	51	51	51	51	52	52	52	52	52	52	52	52	53	53	53	53	53	53	53	54	55	56	63	67
Casirivimab/Imdevimab	0	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	27	27	28	34	38

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-5-km-plot-subgrp-ttdet15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration - Sensitivity Analysis
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	570	534	518	507	498	487	477	473	470	466	466	464	463	459	457	453	452	449	446	443	442	440	440	439	433	425	414	372
Casirivimab/Imdevimab	1192	1192	590	546	533	524	516	510	507	504	501	500	500	499	496	495	494	492	491	488	484	481	481	478	472	470	467	457	450	398

Patients Censored

Placebo	0	623	627	630	630	632	636	640	640	642	644	644	646	647	649	650	652	653	656	659	661	661	662	662	663	669	677	688	728	769
Casirivimab/Imdevimab	0	602	604	606	609	609	613	615	616	618	618	618	618	619	620	621	622	622	624	627	629	629	632	638	640	643	653	660	712	765

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-6-km-plot-ttdets15.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first deterioration - Sensitivity Analysis

Model: Stratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo									
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event				log-rank	Hazard Ratio										
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status					
All	n/a	1192	100	83	6,963	1109	93,037	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	0,1849	0,823	0,614	1,104	Convergence criterion (GCONV=1E-8) satisfied.

Stratification factor = Country.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

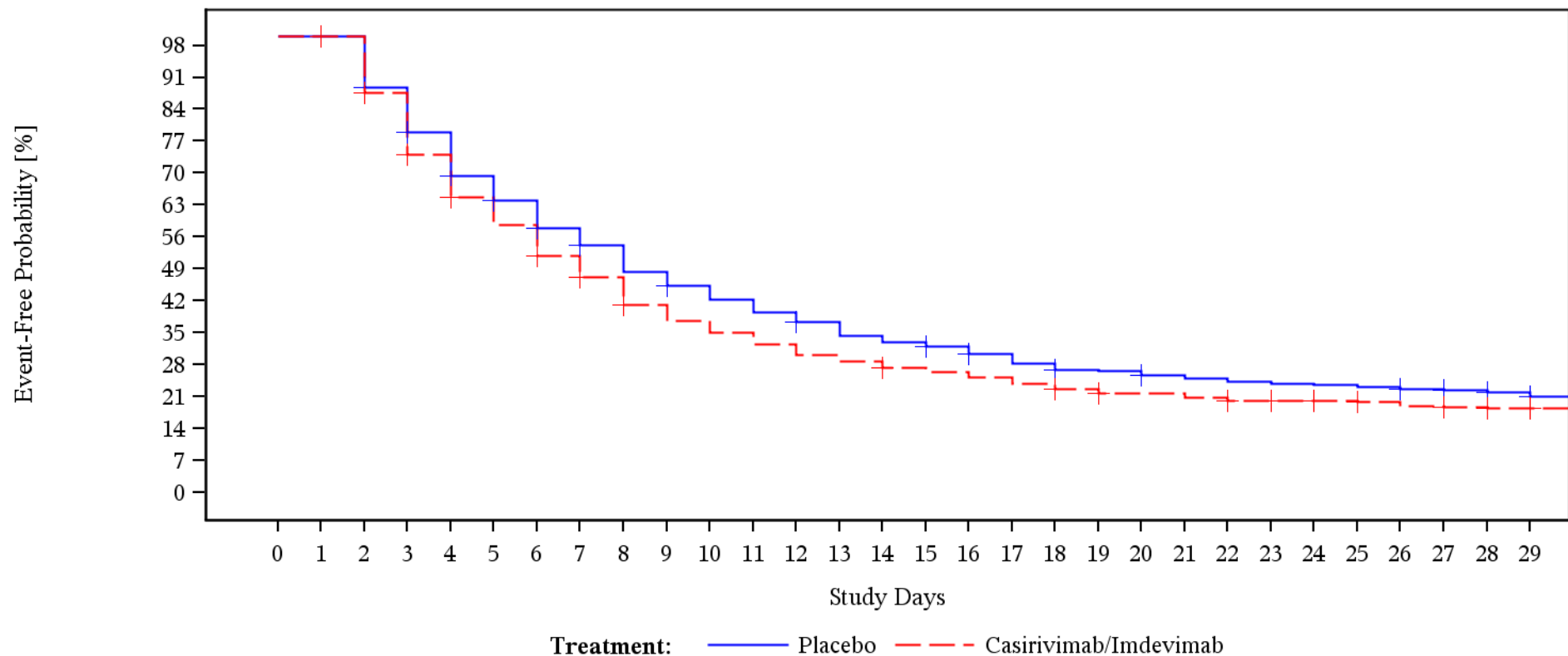
* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas

Output: t13-6-eff-tte-TTDETS15

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	570	502	446	389	358	323	301	268	249	233	217	205	188	180	174	164	153	145	143	137	133	130	127	126	124	119	116	107
Casirivimab/Imdevimab	1192	1192	590	515	434	377	341	300	271	235	215	201	186	173	165	154	149	142	135	127	120	120	115	110	107	106	103	99	95	86

Patients Censored

Placebo	0	623	627	628	630	631	632	634	634	636	636	636	637	637	637	638	639	639	640	640	641	641	641	641	641	641	641	643	645	651	654
Casirivimab/Imdevimab	0	602	604	605	608	608	610	612	613	613	613	613	613	613	613	615	615	615	615	616	618	618	618	619	622	623	624	624	626	634	646

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-timp15.pdf

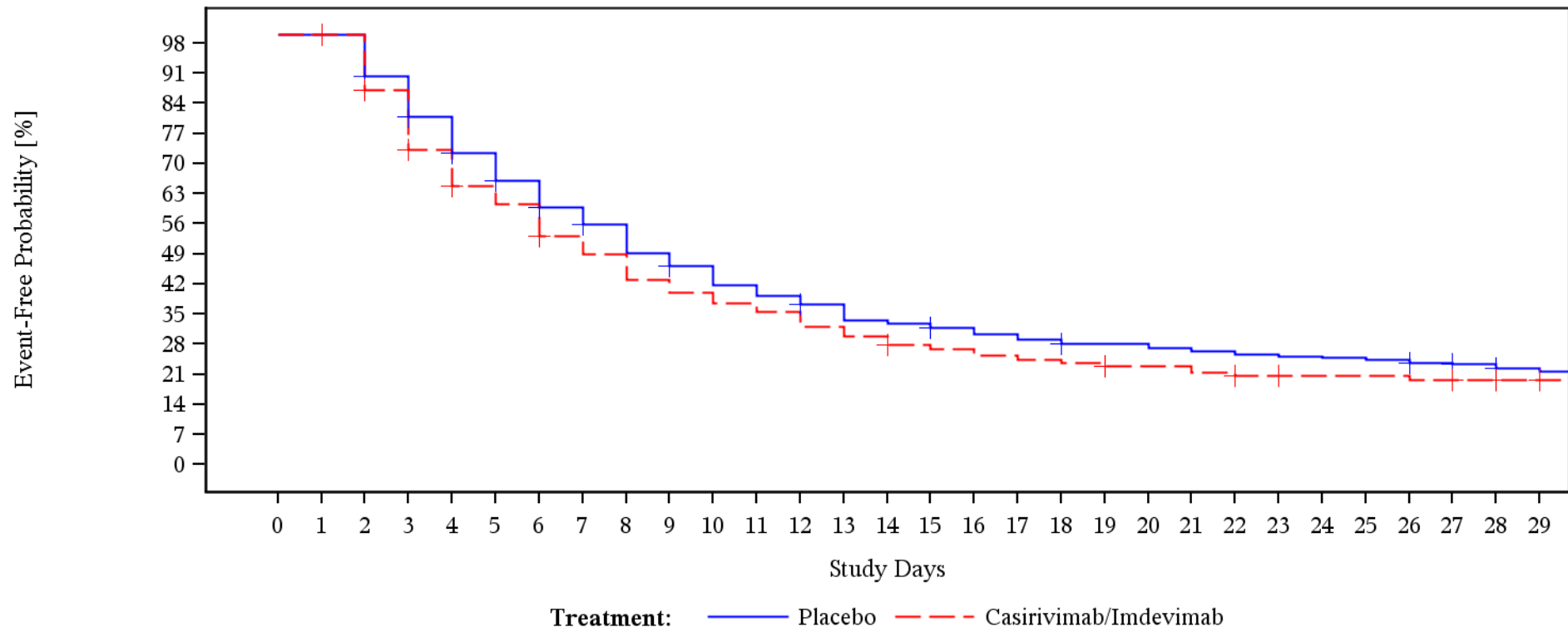
POPULATION: Modified Full Analysis Set
ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
Model: Stratified analysis
STUDY: R10933-10987-COV-2067
Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab										Placebo										Casirivimab/Imdevimab vs. Placebo										
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status		
All	n/a	1192	100	482	40,436	710	59,564	3	3	4	7	6	8	1193	100	462	38,726	731	61,274	4	NE	NE	8	8	9	0,0782	1,116	0,982	1,268	Convergence criterion (GCONV=1E-8) satisfied.		

Stratification factor = Country.
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
 * indicates convergence problem. Result is uninterpretable
 Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas
 Output: t13-7-eff-tte-TTIMP15

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

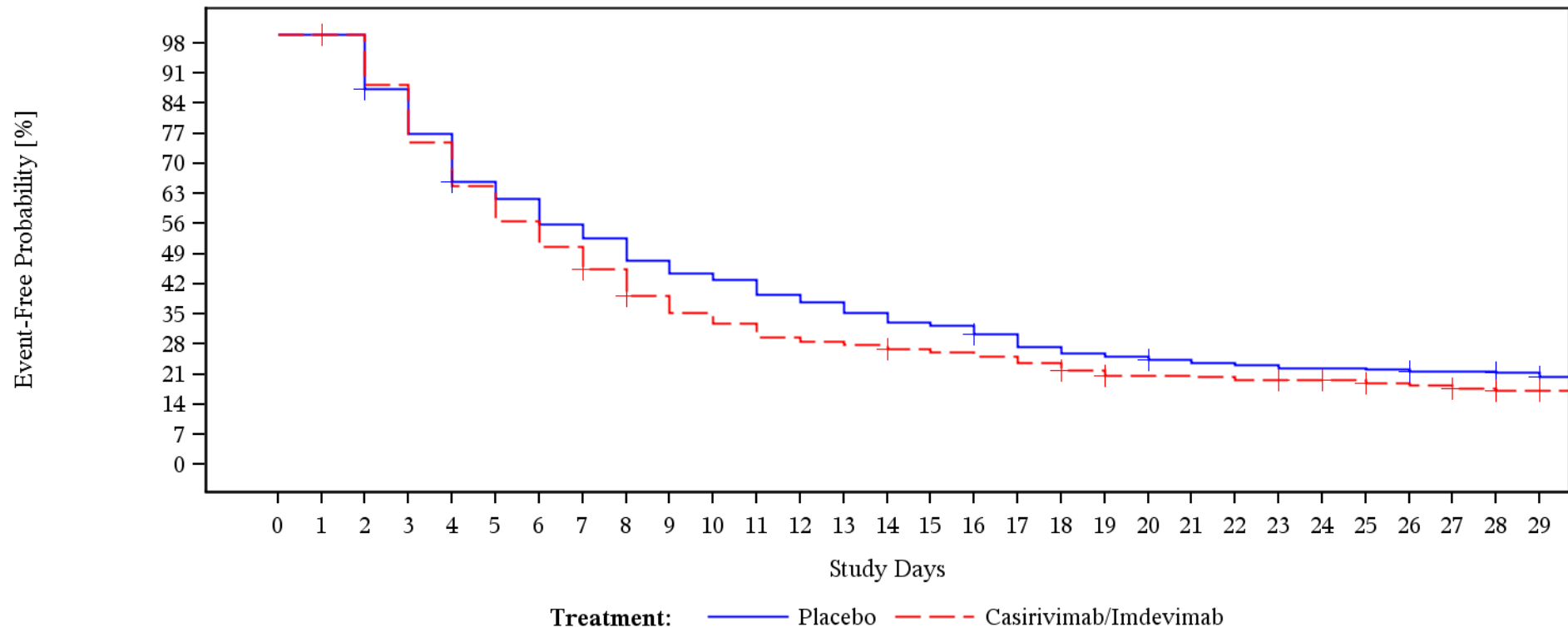
Placebo	580	580	296	265	237	211	191	172	159	140	129	117	110	103	93	91	87	83	80	76	76	73	71	69	68	67	66	63	60	55
Casirivimab/Imdevimab	579	579	300	259	217	189	177	153	141	124	115	108	102	92	86	79	76	72	69	67	64	64	60	57	55	55	55	52	51	47

Patients Censored

Placebo	0	284	286	287	288	289	290	292	292	294	294	294	295	295	295	296	296	296	297	297	297	297	297	297	297	297	297	298	300	303	303
Casirivimab/Imdevimab	0	279	281	282	285	285	287	287	287	287	287	287	287	287	288	288	288	288	288	289	289	289	290	292	292	292	292	292	293	297	303

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

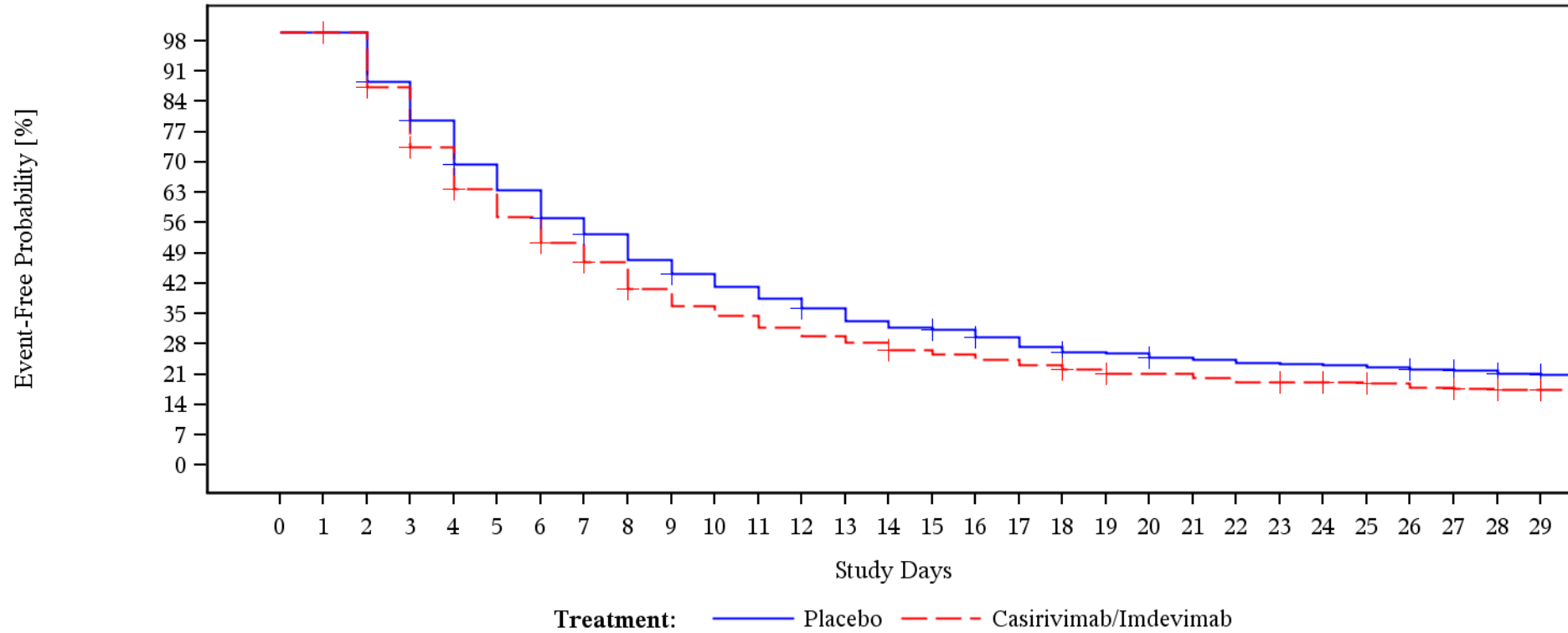
Placebo	613	613	274	237	209	178	167	151	142	128	120	116	107	102	95	89	87	81	73	69	67	64	62	61	59	59	58	56	56	52
Casirivimab/Imdevimab	613	613	290	256	217	188	164	147	130	111	100	93	84	81	79	75	73	70	66	60	56	56	55	53	52	51	48	47	44	39

Patients Censored

Placebo	0	339	341	341	342	342	342	342	342	342	342	342	342	342	342	342	343	343	343	343	344	344	344	344	344	344	345	345	348	351	
Casirivimab/Imdevimab	0	323	323	323	323	323	323	325	326	326	326	326	326	326	327	327	327	327	328	329	329	329	329	329	330	331	332	332	333	337	343

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

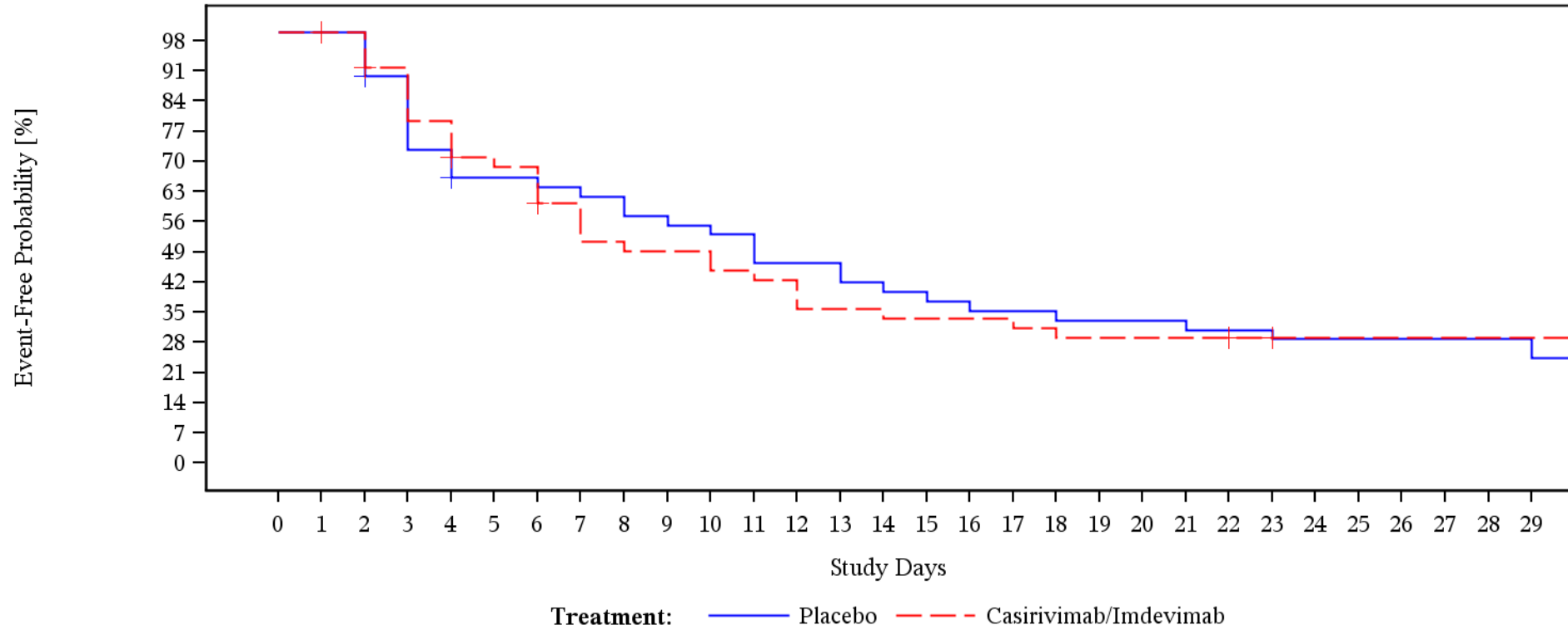
Placebo	1051	1051	513	453	406	353	323	289	268	238	220	205	192	180	165	158	154	145	134	127	125	119	117	114	112	111	109	104	101	92
Casirivimab/Imdevimab	1043	1043	524	457	383	331	297	265	240	207	187	176	162	152	144	134	129	122	116	110	103	103	98	94	92	91	88	84	80	72

Patients Censored

Placebo	0	538	540	541	542	542	543	545	545	547	547	547	548	548	548	549	550	550	551	551	552	552	552	552	552	552	554	556	562	565
Casirivimab/Imdevimab	0	519	520	521	523	523	524	526	527	527	527	527	527	527	529	529	529	529	530	532	532	532	532	534	535	536	536	538	545	556

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

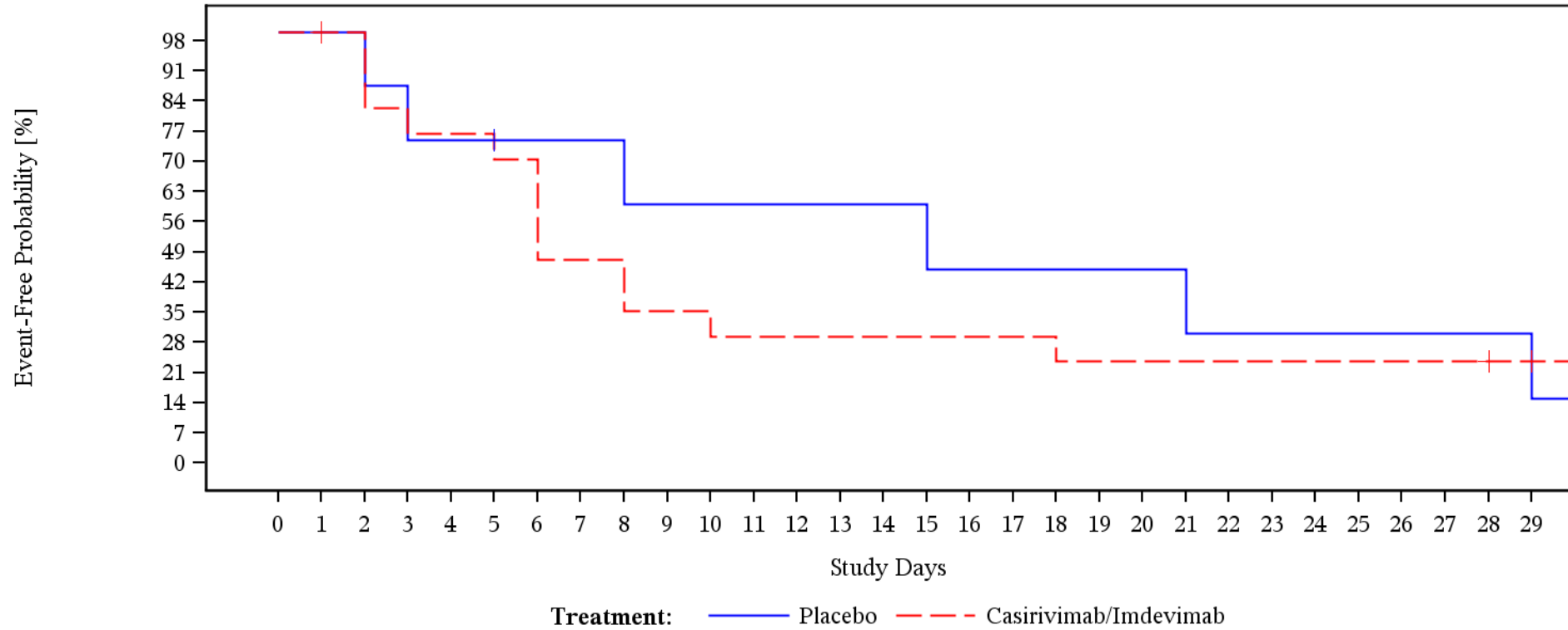
Placebo	108	108	49	42	34	30	30	29	28	26	25	24	21	21	19	18	17	16	16	15	15	15	14	14	13	13	13	13	13	13
Casirivimab/Imdevimab	100	100	49	44	38	33	32	27	23	22	22	20	19	16	16	15	15	15	14	13	13	13	13	12	11	11	11	11	11	11

Patients Censored

Placebo	0	59	61	61	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62	62
Casirivimab/Imdevimab	0	51	52	52	53	53	54	54	54	54	54	54	54	54	54	54	54	54	54	54	54	54	54	54	55	56	56	56	56	56

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

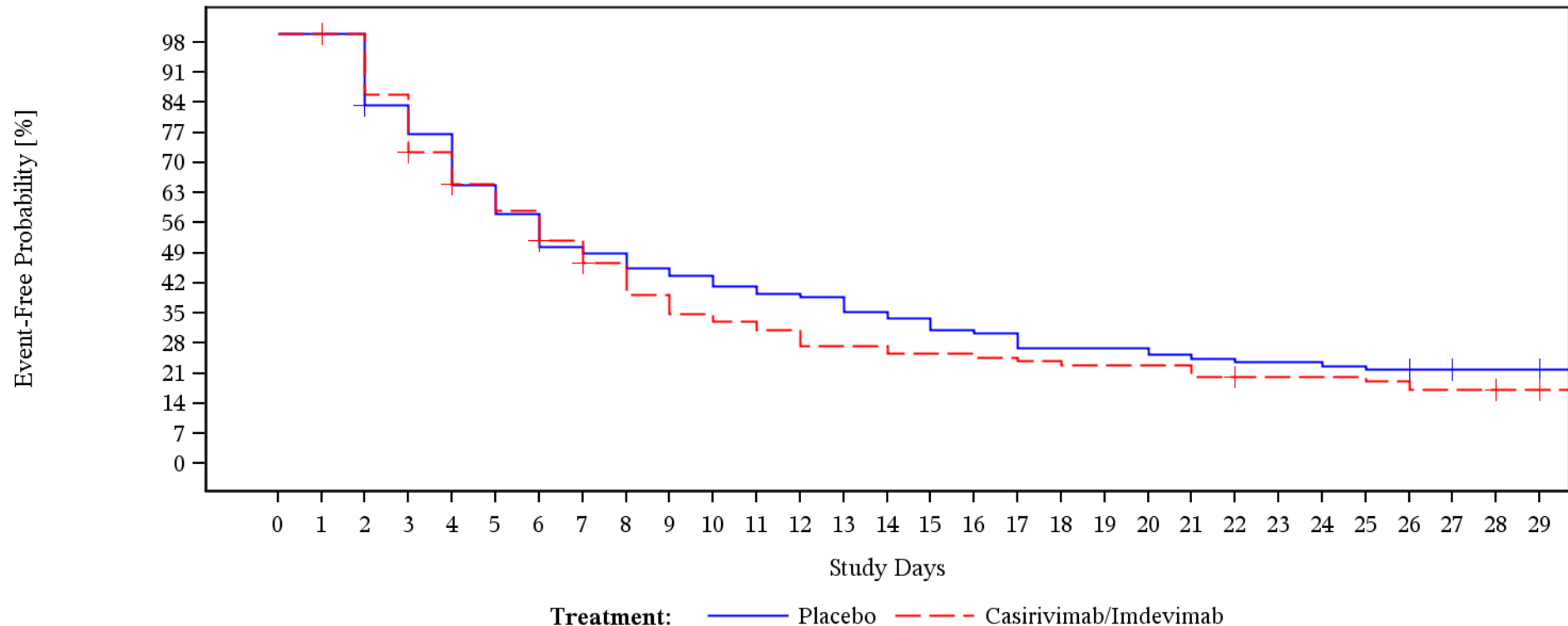
Placebo	34	34	8	7	6	6	5	5	5	4	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	2	2
Casirivimab/Imdevimab	49	49	17	14	13	13	12	8	8	6	6	5	5	5	5	5	5	4	4	4	4	4	4	4	4	4	3

Patients Censored

Placebo	0	26	26	26	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	
Casirivimab/Imdevimab	0	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	33	34

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

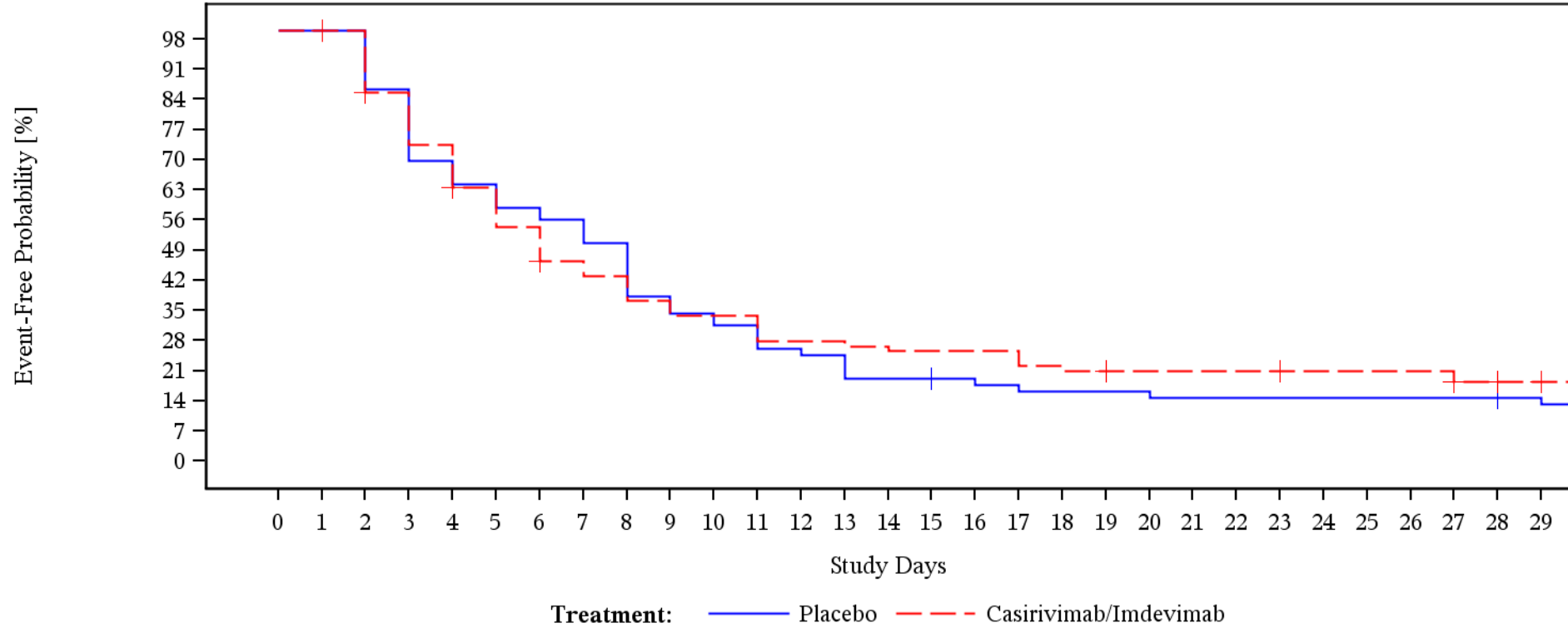
Placebo	242	242	120	99	91	77	69	60	58	54	52	49	47	46	42	40	37	36	32	32	30	29	28	28	27	26	25	24	24	
Casirivimab/Imdevimab	260	260	120	103	86	75	68	59	51	43	38	36	34	30	30	28	28	27	26	25	25	25	22	21	21	21	20	18	18	16

Patients Censored

Placebo	0	122	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	123	124	125	125	127
Casirivimab/Imdevimab	0	140	140	141	143	143	144	146	146	146	146	146	146	146	146	146	146	146	146	146	146	146	147	147	147	147	147	147	149	154

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

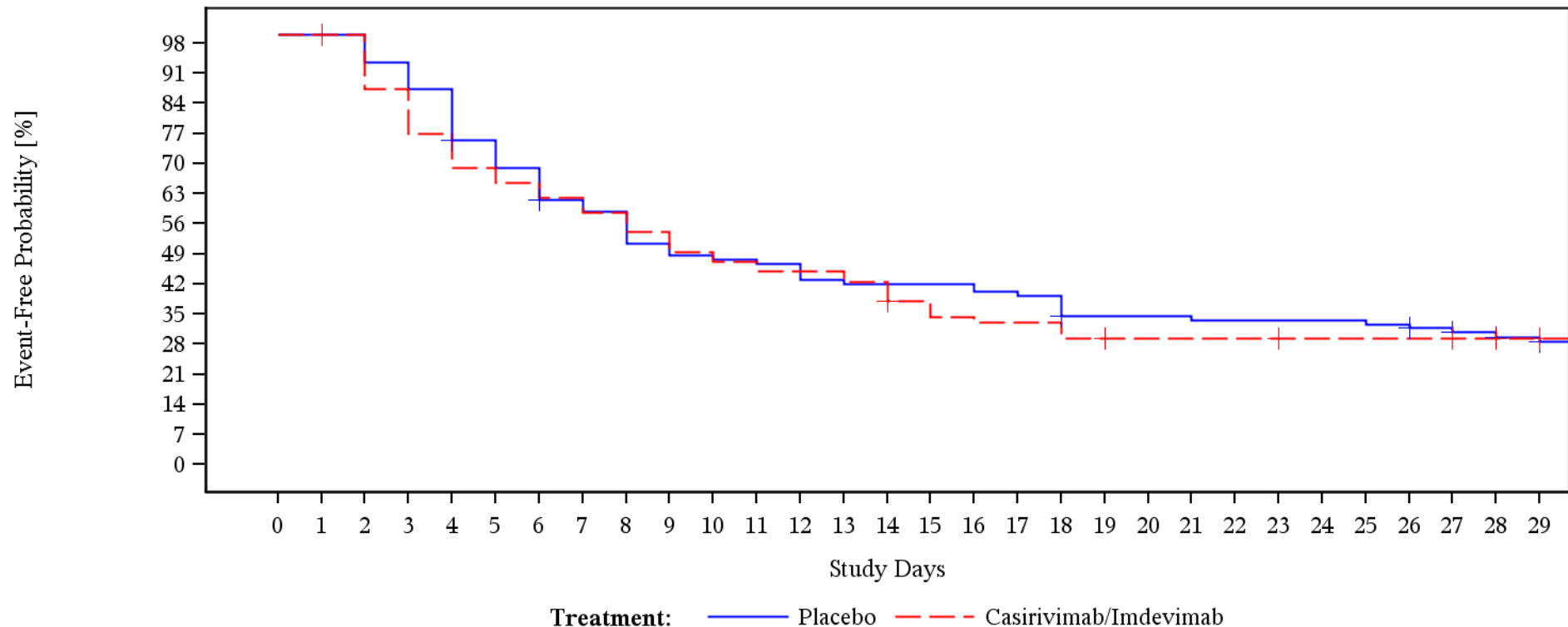
Placebo	183	183	73	63	51	47	43	41	37	28	25	23	19	18	14	14	13	12	11	11	11	10	10	10	10	10	10	10	10	9
Casirivimab/Imdevimab	158	158	91	77	66	56	48	40	37	32	29	29	24	24	23	22	22	22	19	18	17	17	17	17	16	16	16	16	13	10

Patients Censored

Placebo	0	110	110	110	110	110	110	110	110	110	110	110	110	110	110	111	111	111	111	111	111	111	111	111	111	111	111	111	111	112	112				
Casirivimab/Imdevimab	0	67	68	68	69	69	70	70	70	70	70	70	70	70	70	70	70	70	70	71	71	71	71	71	71	71	71	71	72	72	72	72	73	76	77

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

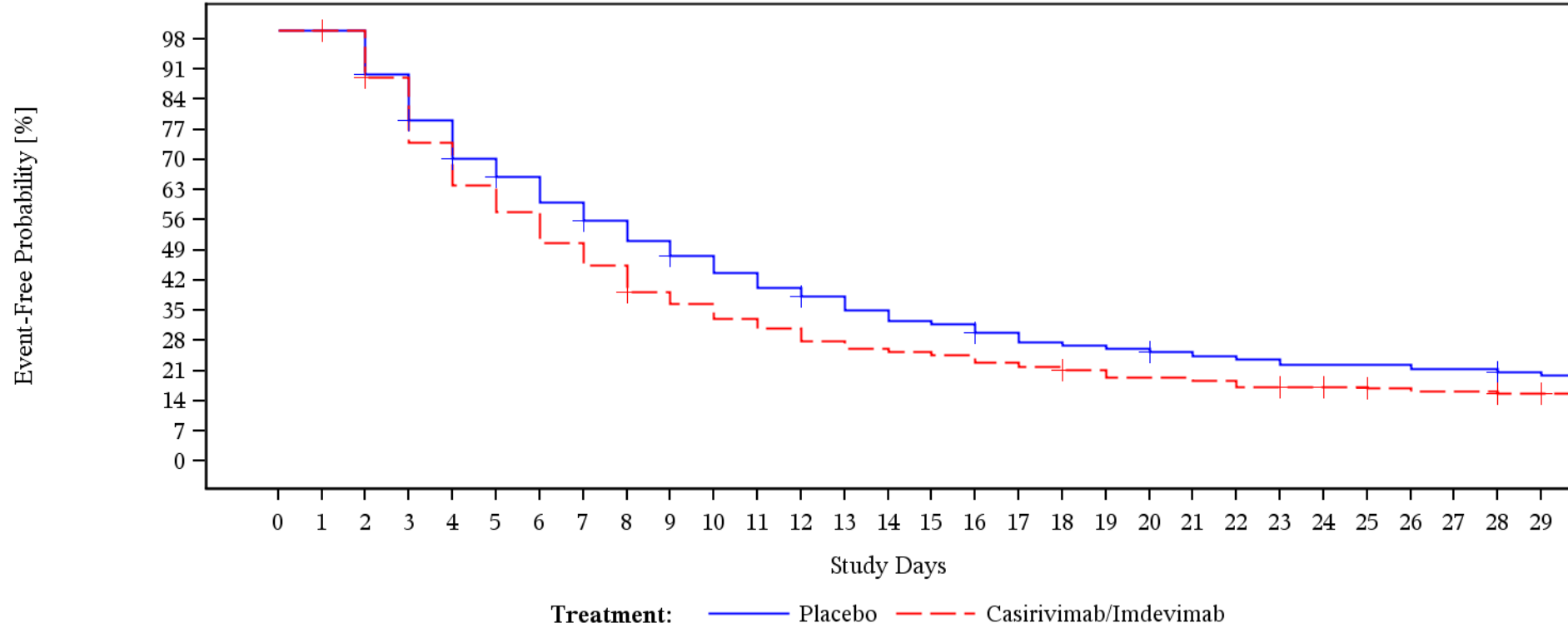
Placebo	205	205	110	103	96	82	75	66	63	55	52	51	50	46	45	45	45	43	42	36	36	36	35	35	35	35	34	32	30	28
Casirivimab/Imdevimab	183	183	87	76	67	60	57	54	51	47	43	41	39	39	37	31	28	27	27	24	23	23	23	23	22	22	22	22	21	20

Patients Censored

Placebo	0	95	95	95	96	96	97	97	97	97	97	97	97	97	97	97	97	97	97	98	98	98	98	98	98	98	98	98	98	98	99	100	101	102
Casirivimab/Imdevimab	0	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96	96

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

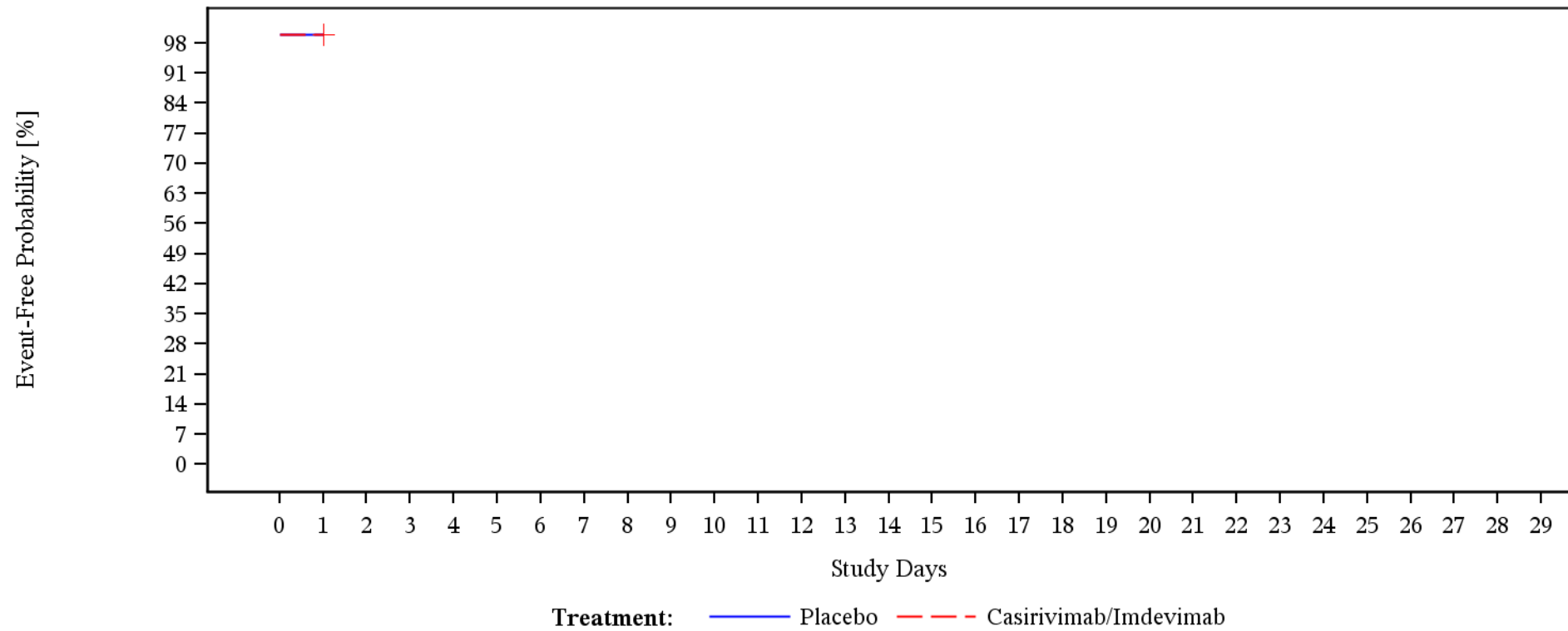
Placebo	561	561	267	237	208	183	171	156	143	131	120	110	101	95	87	81	79	73	68	66	64	61	59	57	54	54	54	52	52	46
Casirivimab/Imdevimab	590	590	292	259	215	186	168	147	132	113	105	95	89	80	75	73	71	66	63	60	55	55	53	49	48	47	45	43	43	40

Patients Censored

Placebo	0	294	297	298	299	300	300	302	302	304	304	304	305	305	305	305	306	306	306	306	307	307	307	307	307	307	307	307	311	311
Casirivimab/Imdevimab	0	298	299	299	299	299	299	299	300	300	300	300	300	300	300	300	300	301	301	301	301	301	301	302	303	304	304	304	306	310

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=Unknown



Patients At Risk

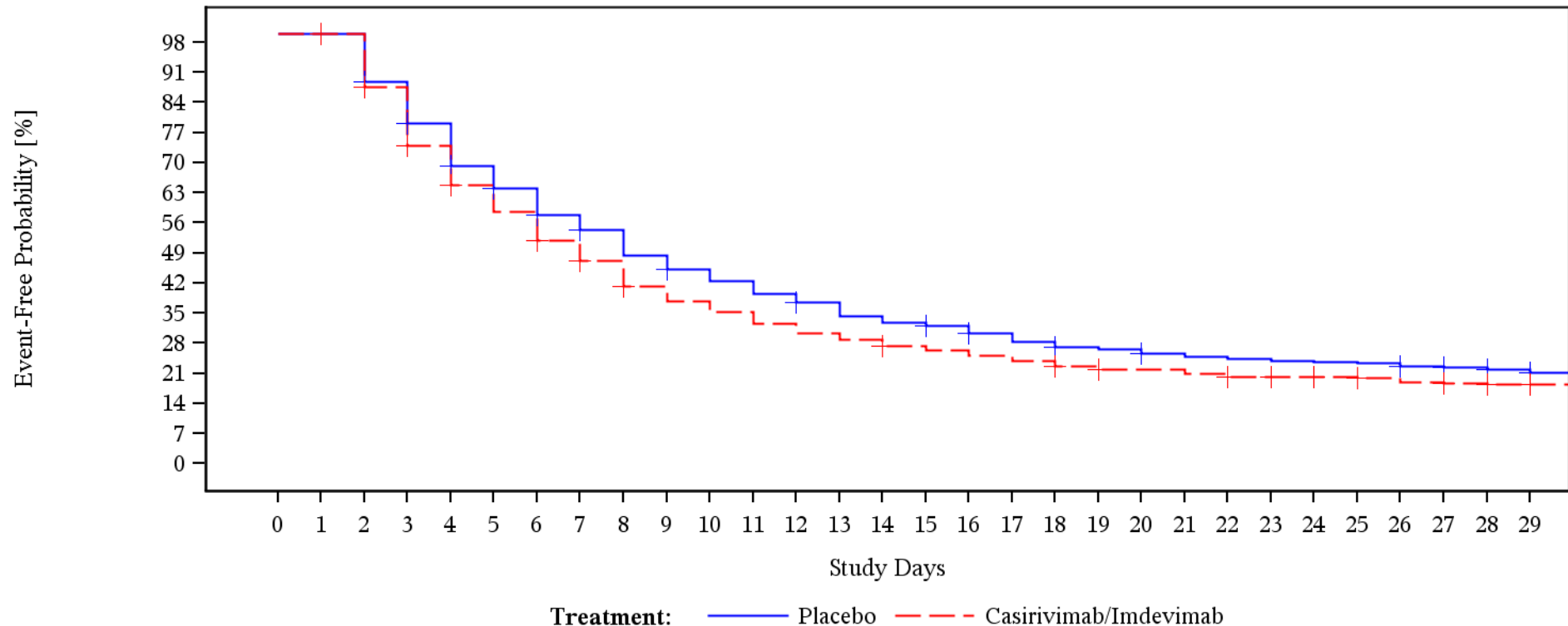
Placebo	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Casirivimab/Imdevimab	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

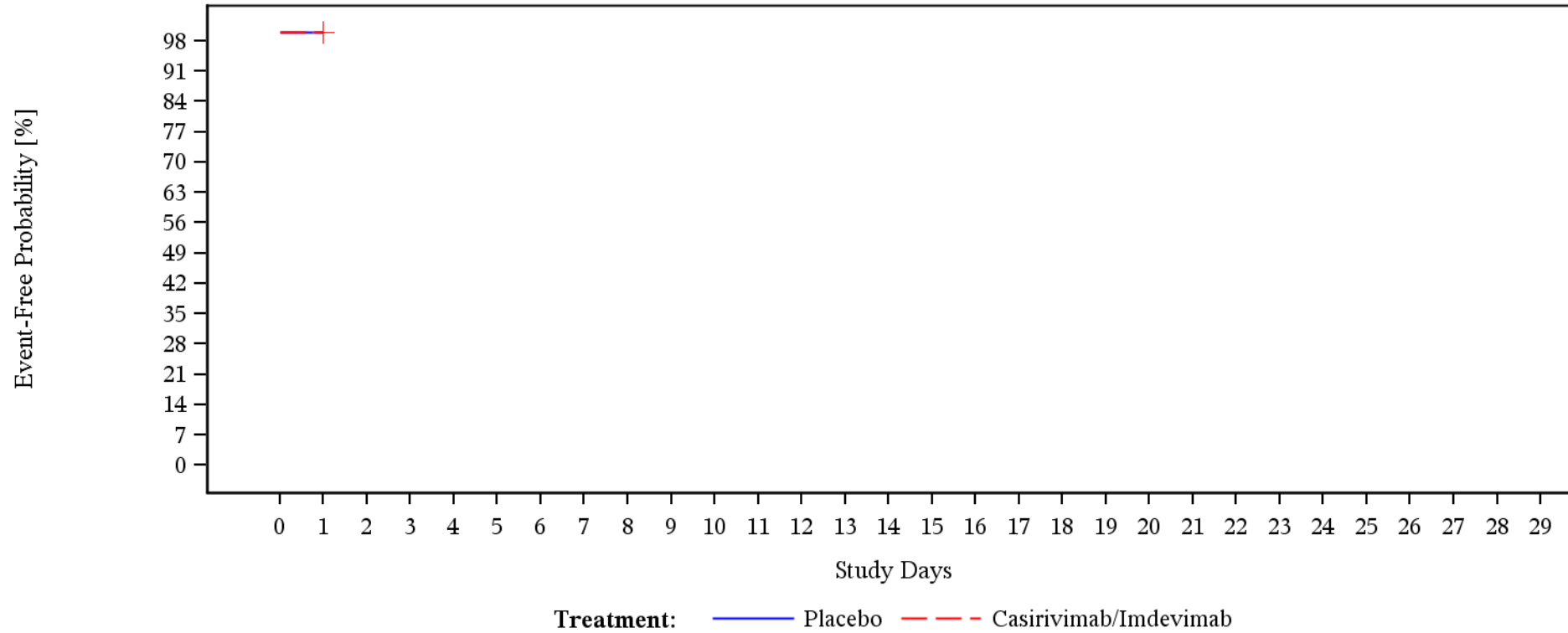
Placebo	1112	1112	570	502	446	389	358	323	301	268	249	233	217	205	188	180	174	164	153	145	143	137	133	130	127	126	124	119	116	107
Casirivimab/Imdevimab	1116	1116	590	515	434	377	341	300	271	235	215	201	186	173	165	154	149	142	135	127	120	120	115	110	107	106	103	99	95	86

Patients Censored

Placebo	0	542	546	547	549	550	551	553	553	555	555	555	556	556	556	557	558	558	559	559	560	560	560	560	560	560	562	564	570	573
Casirivimab/Imdevimab	0	526	528	529	532	532	534	536	537	537	537	537	537	537	539	539	539	539	540	542	542	542	543	546	547	548	548	550	558	570

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Country=MEX



Patients At Risk

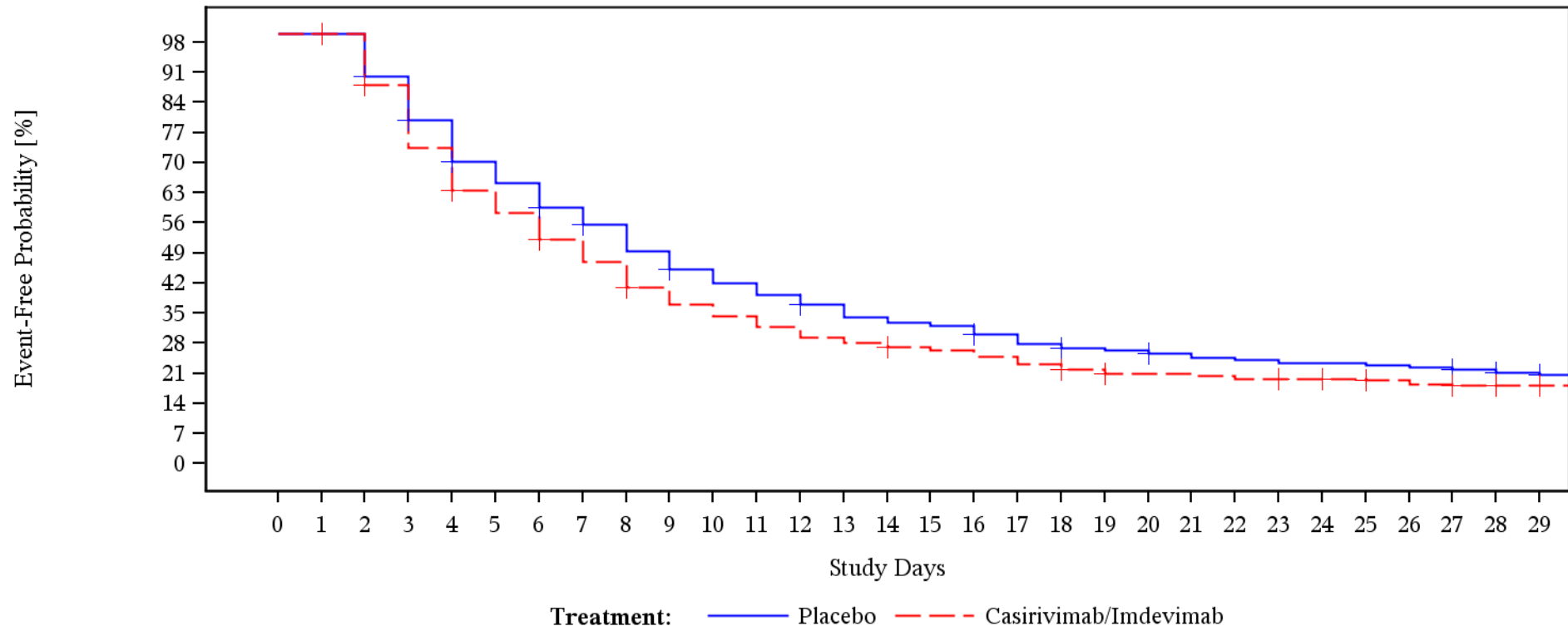
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	
Placebo	81	81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	76	76	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81
Casirivimab/Imdevimab	0	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

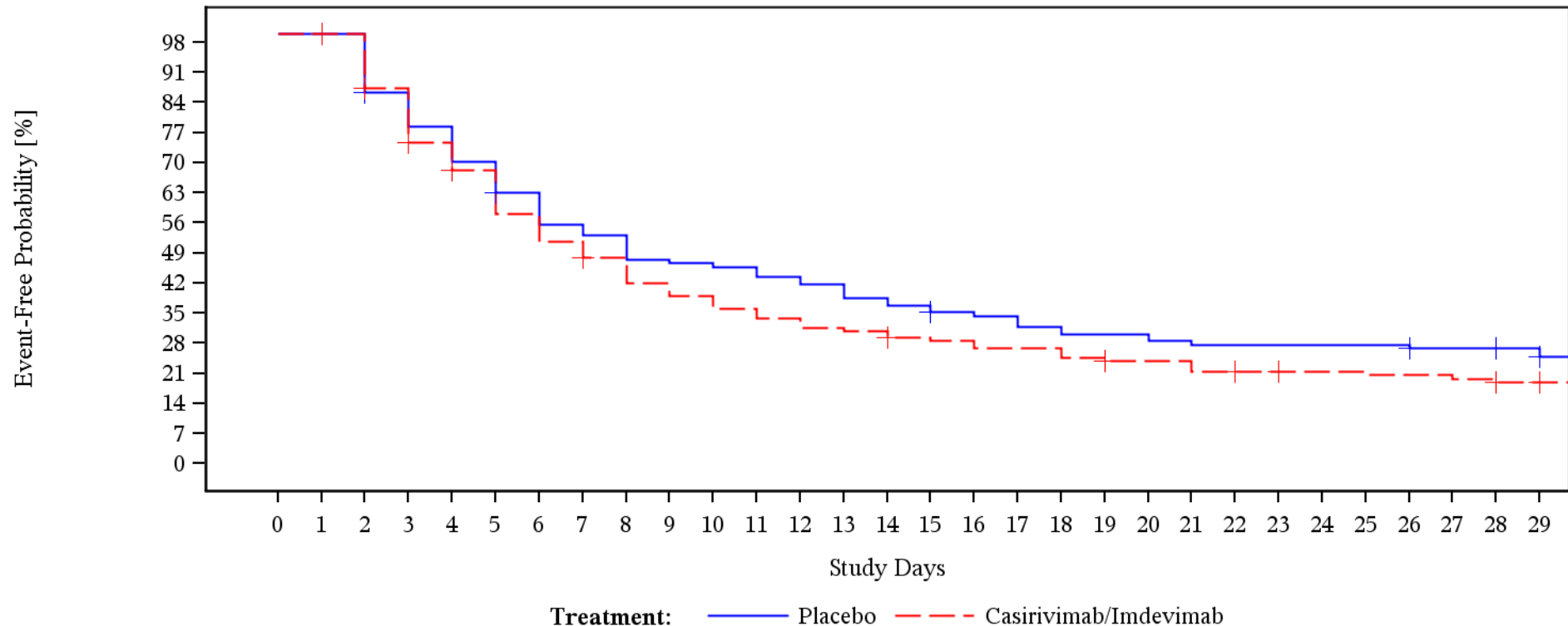
Placebo	813	813	400	357	316	277	257	234	216	192	175	162	152	142	131	126	123	114	106	101	99	95	92	90	87	87	85	83	80	73
Casirivimab/Imdevimab	798	798	390	343	286	246	226	200	180	156	141	131	121	112	107	102	99	94	87	82	77	77	75	72	71	70	68	65	63	60

Patients Censored

Placebo	0	413	416	417	418	418	419	421	421	422	422	422	423	423	423	423	424	424	425	425	426	426	426	426	426	426	426	428	432	433
Casirivimab/Imdevimab	0	408	409	409	410	410	412	412	413	413	413	413	413	413	414	414	414	414	415	416	416	416	416	417	418	419	419	420	423	430

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

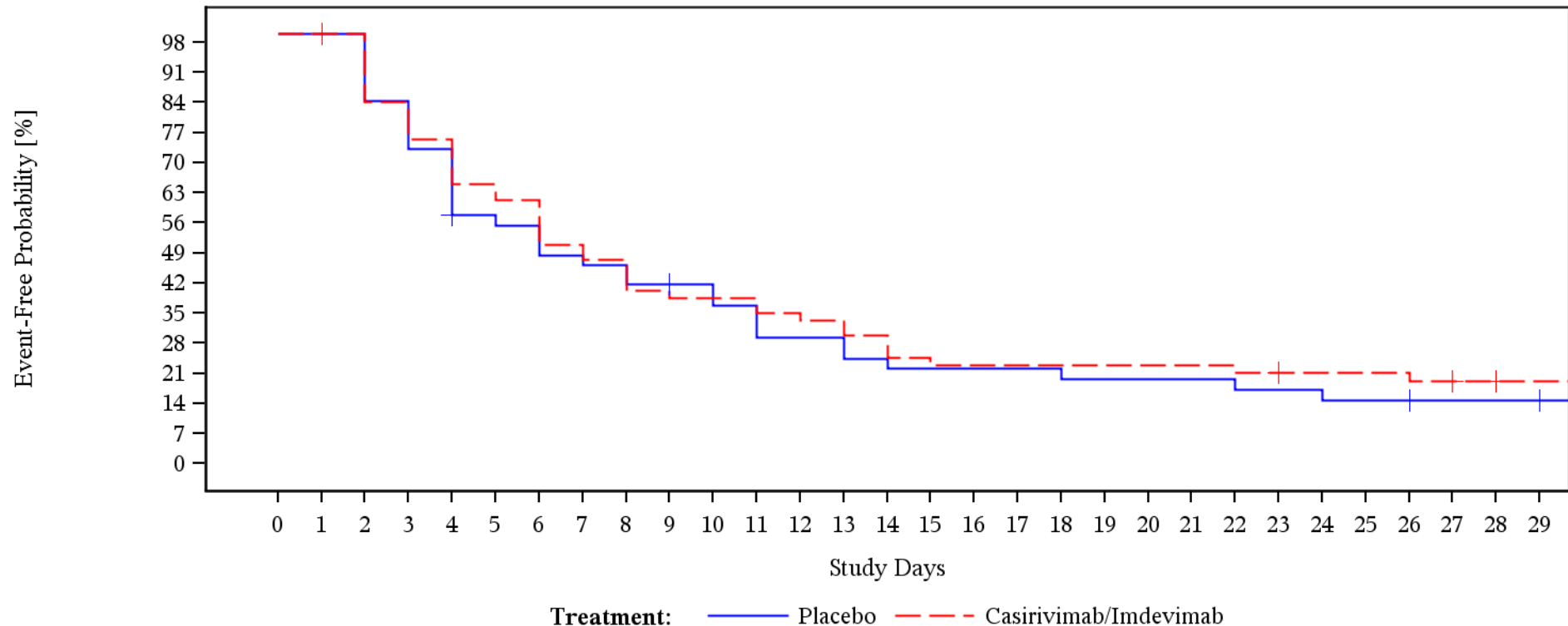
Placebo	284	284	125	107	97	87	77	68	65	58	57	56	53	51	47	45	42	41	38	36	36	34	33	33	33	33	31	31	29	
Casirivimab/Imdevimab	311	311	143	124	105	94	80	71	64	56	52	48	45	42	41	38	37	35	35	32	30	30	27	26	25	25	24	24	23	20

Patients Censored

Placebo	0	159	160	160	160	161	161	161	161	161	161	161	161	161	161	162	162	162	162	162	162	162	162	162	162	162	162	163	163	165	166
Casirivimab/Imdevimab	0	168	169	170	172	172	172	174	174	174	174	174	174	174	174	175	175	175	175	175	175	176	176	176	177	178	178	178	178	180	185

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified FAS Population
 ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	96	96	45	38	33	25	24	21	20	18	17	15	12	12	10	9	9	9	9	8	8	8	8	7	7	6	6	5	5	5
Casirivimab/Imdevimab	83	83	57	48	43	37	35	29	27	23	22	22	20	19	17	14	13	13	13	13	13	13	13	12	11	11	11	10	9	6

Patients Censored

Placebo	0	51	51	51	52	52	52	52	52	53	53	53	53	53	53	53	53	53	53	53	53	53	53	53	53	53	54	54	54	55		
Casirivimab/Imdevimab	0	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	27	27	27	27	27	28	31	31

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-7-km-plot-subgrp-ttimp15.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo										Casirivimab/Imdevimab vs. Placebo					Interaction Test		
		Patients		Patients with Event		Censored		Time to event				Patients		Patients with Event		Censored		Time to event				log-rank	Hazard Ratio				Convergence Status				
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1		95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		p-value		Hazard Ratio	95% Lower CL
All	n/a	1192	100	482	40,436	710	59,564	3	3	4	7	6	8	1193	100	462	38,726	731	61,274	4	NE	NE	8	8	9	0,0782	1,116	0,982	1,268	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	579	48,574	239	41,278	340	58,722	3	3	4	7	6	8	580	48,617	236	40,69	344	59,31	4	4	5	8	8	10	0,2708	1,101	0,92	1,319	Convergence criterion (GCONV=1E-8) satisfied.	0,8263
	Female	613	51,426	243	39,641	370	60,359	3	3	4	7	6	8	613	51,383	226	36,868	387	63,132	4	3	4	8	6	10	0,1711	1,128	0,941	1,353	Convergence criterion (GCONV=1E-8) satisfied.	
Age	18-64	1043	87,5	434	41,611	609	58,389	3	3	4	7	6	8	1051	88,097	419	39,867	632	60,133	4	NE	NE	8	7	9	0,0632	1,129	0,987	1,291	Convergence criterion (GCONV=1E-8) satisfied.	0,8632
	65-74	100	8,389	35	35	65	65	4	3	6	8	6	12	108	9,053	37	34,259	71	65,741	3	3	7	11	6	16	0,9539	0,987	0,621	1,568	Convergence criterion (GCONV=1E-8) satisfied.	
	>=75	49	4,111	13	26,531	36	73,469	5	2	6	6	3	18	34	2,85	6	17,647	28	82,353	5,5	2	21	15	2	29	0,7447	1,166	0,441	3,081	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline viral load categories	<=10^5 copies/mL	260	21,812	98	37,692	162	62,308	3	3	4	7	5	8	242	20,285	98	40,496	144	59,504	4	3	4	7	5	10	0,3202	1,146	0,864	1,52	Convergence criterion (GCONV=1E-8) satisfied.	0,4946
	>10^5 copies/mL - <=10^6 copies/mL	158	13,255	73	46,203	85	53,797	3	3	4	6	5	8	183	15,339	67	36,612	116	63,388	3	3	4	8	5	8	0,4313	0,882	0,632	1,231	Convergence criterion (GCONV=1E-8) satisfied.	
	>10^6 copies/mL - <=10^7 copies/mL	183	15,352	63	34,426	120	65,574	4	3	5	9	7	14	205	17,184	80	39,024	125	60,976	5	4	6	9	7	16	0,7429	1,055	0,758	1,468	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo								
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test			
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)			
	>10 ⁷ copies/mL	590	49,497	248	42,034	342	57,966	3	3	4	7	6	8	561	47,024	217	38,681	344	61,319	4	3	5	9	7	10	0,0638	1,178	0,982	1,414	Convergence criterion (GCONV=1E-8) satisfied.				
	Unknown	1	0,084	0	0	1	100	NE	NE	NE	NE	NE	NE	2	0,168	0	0	2	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Country	USA	1116	93,624	482	43,19	634	56,81	3	3	4	7	6	8	1112	93,21	462	41,547	650	58,453	4	NE	NE	8	8	9	0,0782	1,116	0,982	1,268	Convergence criterion (GCONV=1E-8) satisfied.				
	MEX	76	6,376	0	0	76	100	NE	NE	NE	NE	NE	NE	81	6,79	0	0	81	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	979	82,131	423	43,207	556	56,793	3	3	4	7	6	8	984	82,481	405	41,159	579	58,841	4	3	4	8	7	9	0,1585	1,098	0,958	1,258	Convergence criterion (GCONV=1E-8) satisfied.	0,5769			
	Black or African American	55	4,614	22	40	33	60	5	3	7	9	6	14	51	4,275	18	35,294	33	64,706	4	3	9	12	5	87	0,1853	1,508	0,801	2,84	Convergence criterion (GCONV=1E-8) satisfied.				
	Asian/American Indian Alaska Native/Native Hawaiian or other Pacific Islander	85	7,131	19	22,353	66	77,647	3	2	5	6	3	14	70	5,868	16	22,857	54	77,143	3,5	2	6	8	3	15	0,9842	1,007	0,512	1,977	Convergence criterion (GCONV=1E-8) satisfied.				
	Unknown/Not Reported	73	6,124	18	24,658	55	75,342	4	2	6	7	4	17	88	7,376	23	26,136	65	73,864	6	2	8	9,5	7	13	0,8359	1,065	0,574	1,977	Convergence criterion (GCONV=1E-8) satisfied.				

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: EQ-5D-5L VAS/ MID=15: Time to first improvement

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Baseline serostatus	Negative	798	66,946	324	40,602	474	59,398	3	3	4	7	6	8	813	68,148	326	40,098	487	59,902	4	NE	NE	8	8	10	0,0842	1,138	0,976	1,328	Convergence criterion (GCONV=1E-8) satisfied.	0,9361
	Positive	311	26,091	112	36,013	199	63,987	3	3	5	7	5	9	284	23,806	98	34,507	186	65,493	4	3	5	8	6	13	0,3113	1,143	0,871	1,501	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	83	6,963	46	55,422	37	44,578	4	2	5	7	5	11	96	8,047	38	39,583	58	60,417	3	2	4	6	4	11	0,5347	0,879	0,572	1,352	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

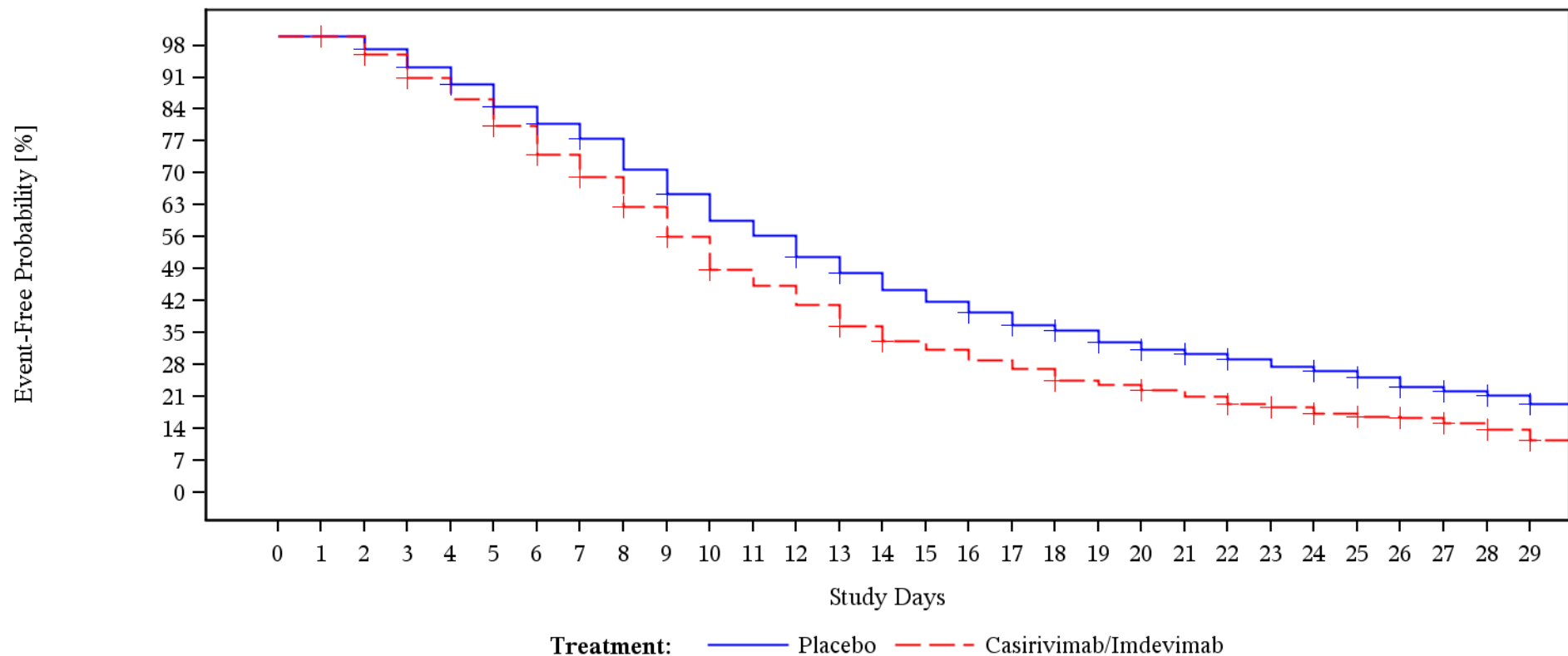
" indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas

Output: t13-7-eff-tte-TTIMP15

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	711	685	656	629	592	563	538	491	450	410	387	354	329	303	286	268	249	239	221	209	201	191	180	173	162	148	133	79
Casirivimab/Imdevimab	1192	1192	739	706	668	634	589	540	503	455	406	352	327	297	262	236	223	206	192	174	166	157	147	135	125	115	109	107	93	59

Patients Censored

Placebo	0	482	488	489	490	492	495	498	498	501	501	501	503	504	504	504	505	506	507	508	510	511	513	513	515	516	517	526	575	646
Casirivimab/Imdevimab	0	453	456	457	457	459	461	463	464	465	466	466	466	467	470	470	470	470	471	471	472	472	474	478	479	480	481	487	513	558

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-ttrtuh.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: Return to usual health: Time to 'Yes'

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					
Name	Level	Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank p-value	Hazard Ratio				Interaction Test p-value (likelihood ratio)
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status (GCONV=1E-8) satisfied.	
All	n/a	1192	100	633	53,104	559	46,896	6	6	7	10	10	11	1193	100	547	45,851	646	54,149	8	7	8	13	12	14	<.0001	1,316	1,173	1,476	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	579	48,574	324	55,959	255	44,041	6	5	7	10	9	10	580	48,617	270	46,552	310	53,448	8	7	9	13	12	14	<.0001	1,415	1,203	1,664	Convergence criterion (GCONV=1E-8) satisfied.	0,2256
	Female	613	51,426	309	50,408	304	49,592	7	6	8	12	10	13	613	51,383	277	45,188	336	54,812	8	7	8	13	12	14	0,01	1,229	1,045	1,446	Convergence criterion (GCONV=1E-8) satisfied.	
Age	18-64	1043	87,5	562	53,883	481	46,117	6	6	7	10	10	11	1051	88,097	498	47,383	553	52,617	8	7	8	13	12	14	<.0001	1,268	1,123	1,43	Convergence criterion (GCONV=1E-8) satisfied.	0,2063
	65-74	100	8,389	50	50	50	50	6	4	7	11	7	13	108	9,053	42	38,889	66	61,111	8	6	12	18	13	26	0,0055	1,756	1,16	2,657	Convergence criterion (GCONV=1E-8) satisfied.	
	>=75	49	4,111	21	42,857	28	57,143	3	2	6	8	6	13	34	2,85	7	20,588	27	79,412	4	3	21	18	4	NE	0,1249	1,898	0,797	4,518	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline viral load categories	<=10^5 copies/mL	260	21,812	126	48,462	134	51,538	5	4	6	10	8	12	242	20,285	114	47,107	128	52,893	5	4	7	11	9	14	0,6475	1,058	0,821	1,364	Convergence criterion (GCONV=1E-8) satisfied.	0,0977
	>10^5 copies/mL - <=10^6 copies/mL	158	13,255	84	53,165	74	46,835	7	5	9	10	9	13	183	15,339	72	39,344	111	60,656	7	5	8	12,5	9	16	0,0999	1,292	0,941	1,774	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
 * indicates convergence problem. Result is uninterpretable
 Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: Return to usual health: Time to 'Yes'

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
	>10^6 copies/mL - <=10^7 copies/mL	183	15,352	102	55,738	81	44,262	7	6	8	11	10	13	205	17,184	107	52,195	98	47,805	8	6	9	13	12	15	0,2989	1,149	0,876	1,507	Convergence criterion (GCONV=1E-8) satisfied.		
	>10^7 copies/mL	590	49,497	320	54,237	270	45,763	6	6	7	10	9	12	561	47,024	252	44,92	309	55,08	9	8	10	14	12	16	<.0001	1,518	1,286	1,792	Convergence criterion (GCONV=1E-8) satisfied.		
	Unknown	1	0,084	1	100	0	0	18	NE	NE	18	NE	NE	2	0,168	2	100	0	0	8	8	13	10,5	8	13	0,2253	0	0	NE	Convergence criterion (GCONV=1E-8) satisfied.		
Country	USA	1116	93,624	633	56,72	483	43,28	6	6	7	10	10	11	1112	93,21	547	49,191	565	50,809	8	7	8	13	12	14	<.0001	1,316	1,173	1,476	Convergence criterion (GCONV=1E-8) satisfied.		
	MEX	76	6,376	0	0	76	100	NE	NE	NE	NE	NE	NE	81	6,79	0	0	81	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	979	82,131	555	56,691	424	43,309	6	6	7	10	10	12	984	82,481	473	48,069	511	51,931	8	7	8	13	12	14	<.0001	1,301	1,15	1,471	Convergence criterion (GCONV=1E-8) satisfied.	0,6922	
	Black or African American	55	4,614	33	60	22	40	6	4	8	9	7	12	51	4,275	27	52,941	24	47,059	5	3	10	13	9	20	0,0505	1,651	0,977	2,79	Convergence criterion (GCONV=1E-8) satisfied.		
	Asian/American Indian/Alaska Native/Native Hawaiian or other Pacific Islander	85	7,131	27	31,765	58	68,235	6	3	9	10	8	13	70	5,868	24	34,286	46	65,714	9	4	12	13	9	17	0,2988	1,326	0,764	2,302	Convergence criterion (GCONV=1E-8) satisfied.		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: Return to usual health: Time to 'Yes'

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

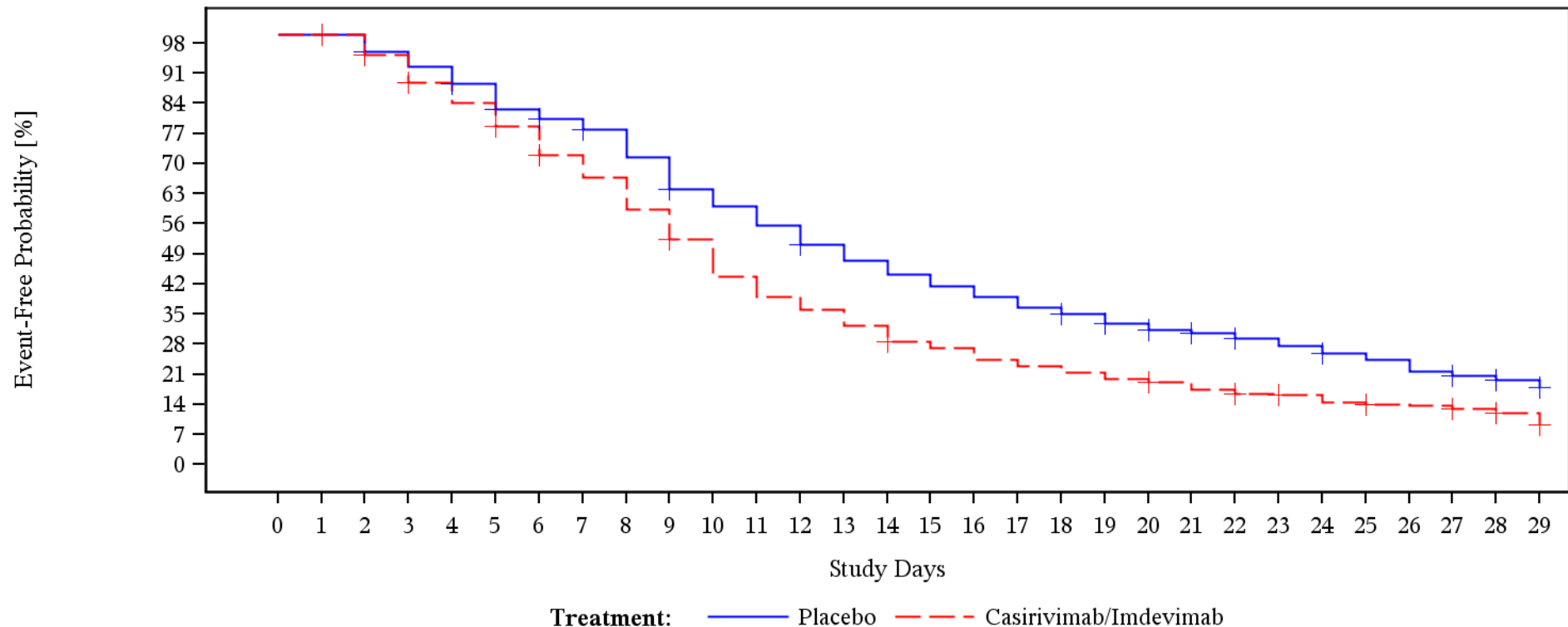
		Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					
Name	Level	Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank p-value	Hazard Ratio				Interaction Test p-value (likelihood ratio)
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status (GCONV=1E-8)	
	Unknown/Not Reported	73	6,124	18	24,658	55	75,342	6	2	8	9	6	12	88	7,376	23	26,136	65	73,864	7	3	10	12	8	16	0,3955	1,296	0,697	2,41	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline serostatus	Negative	798	66,946	437	54,762	361	45,238	7	6	8	10	10	11	813	68,148	385	47,355	428	52,645	8	8	9	13	12	14	<.0001	1,375	1,198	1,577	Convergence criterion (GCONV=1E-8) satisfied.	0,3979
	Positive	311	26,091	142	45,659	169	54,341	5	5	6	10	9	12	284	23,806	119	41,901	165	58,099	6	5	8	13	10	15	0,1202	1,204	0,944	1,537	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	83	6,963	54	65,06	29	34,94	6	4	7	9	8	12	96	8,047	43	44,792	53	55,208	6	5	8	9	8	14	0,6067	1,106	0,74	1,655	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

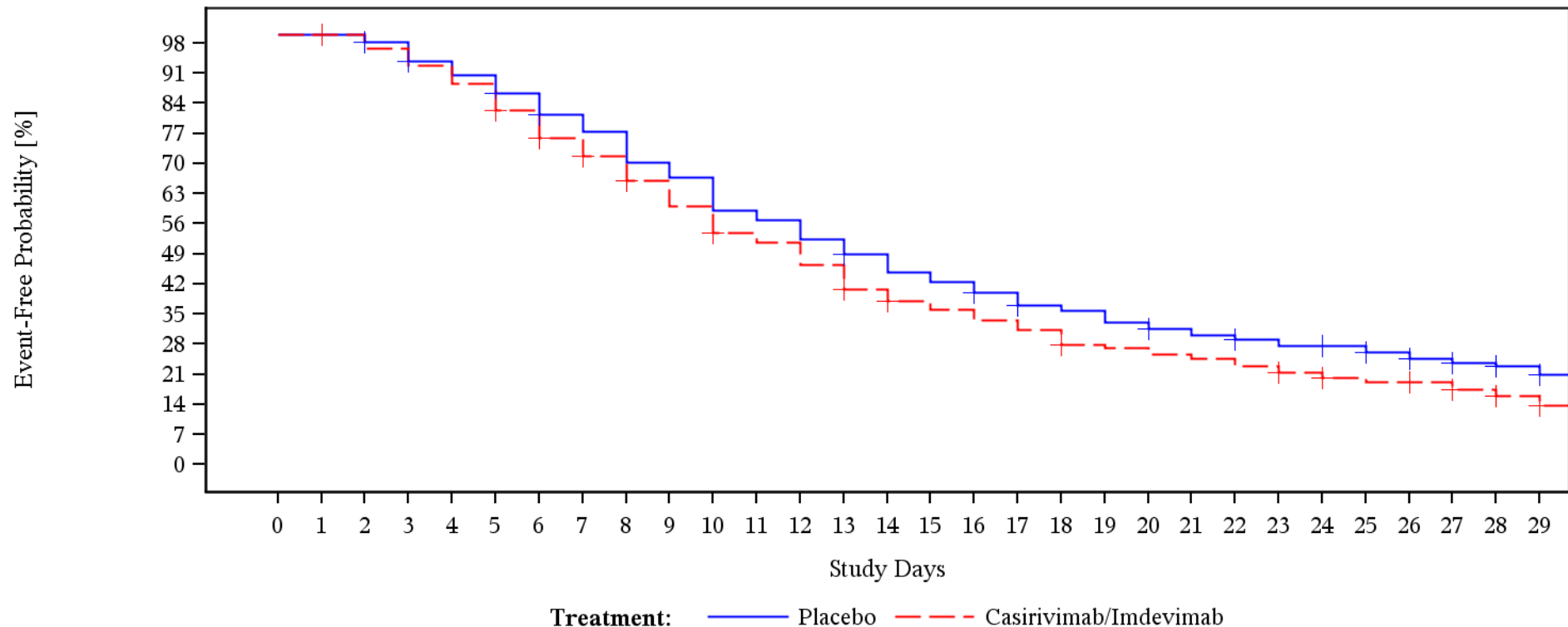
Placebo	580	580	349	332	320	305	284	274	263	241	213	200	185	168	156	145	136	128	120	114	106	100	97	92	86	80	75	67	58	36
Casirivimab/Imdevimab	579	579	372	351	327	309	288	263	244	217	190	159	142	131	117	103	97	88	82	77	72	68	62	56	52	47	44	43	39	22

Patients Censored

Placebo	0	231	234	234	235	236	238	241	241	244	244	244	246	246	246	246	246	246	247	248	249	250	251	251	252	252	252	258	277	310
Casirivimab/Imdevimab	0	207	210	211	211	212	213	213	213	214	214	214	214	214	215	215	215	215	215	215	216	216	218	221	221	222	222	224	238	255

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

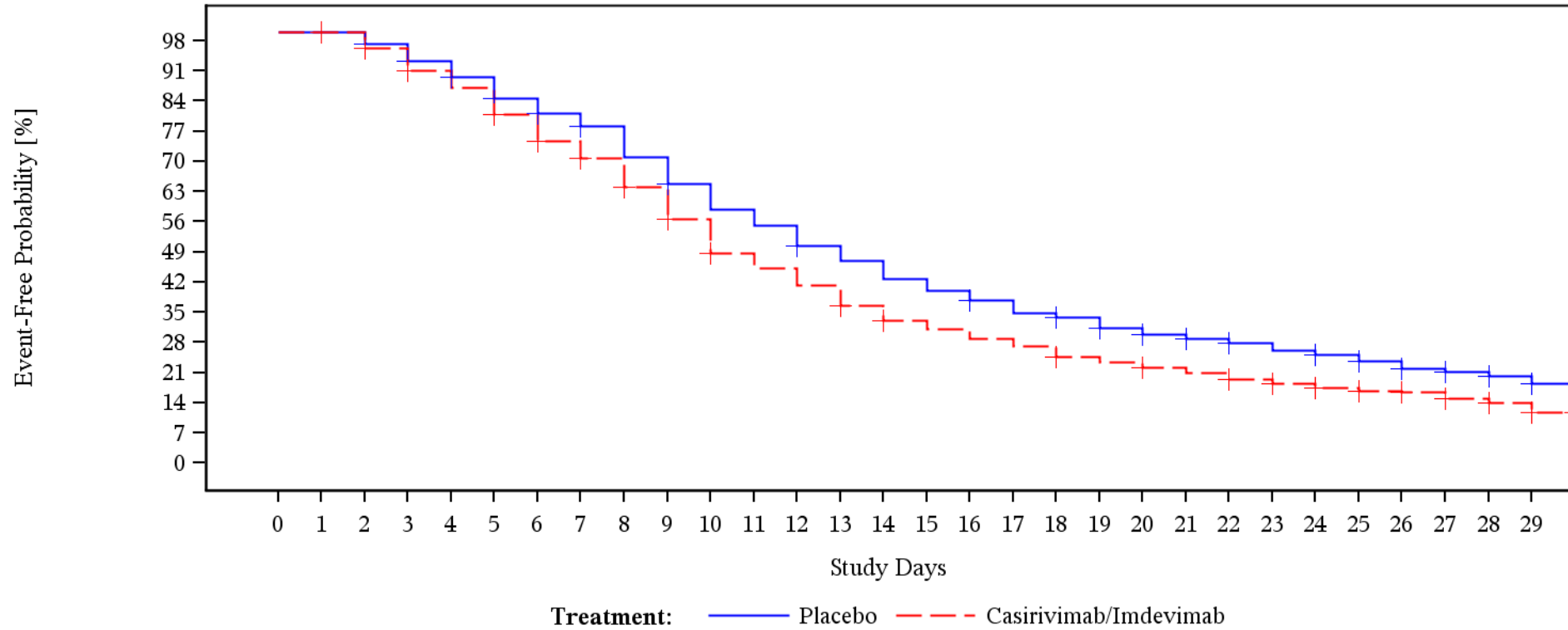
Placebo	613	613	362	353	336	324	308	289	275	250	237	210	202	186	173	158	150	140	129	125	115	109	104	99	94	93	87	81	75	43
Casirivimab/Imdevimab	613	613	367	355	341	325	301	277	259	238	216	193	185	166	145	133	126	118	110	97	94	89	85	79	73	68	65	64	54	37

Patients Censored

Placebo	0	251	254	255	255	256	257	257	257	257	257	257	257	258	258	258	259	260	260	260	261	261	262	262	263	264	265	268	298	336
Casirivimab/Imdevimab	0	246	246	246	246	247	248	250	251	251	252	252	252	253	255	255	255	255	256	256	256	256	256	257	258	258	259	263	275	303

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

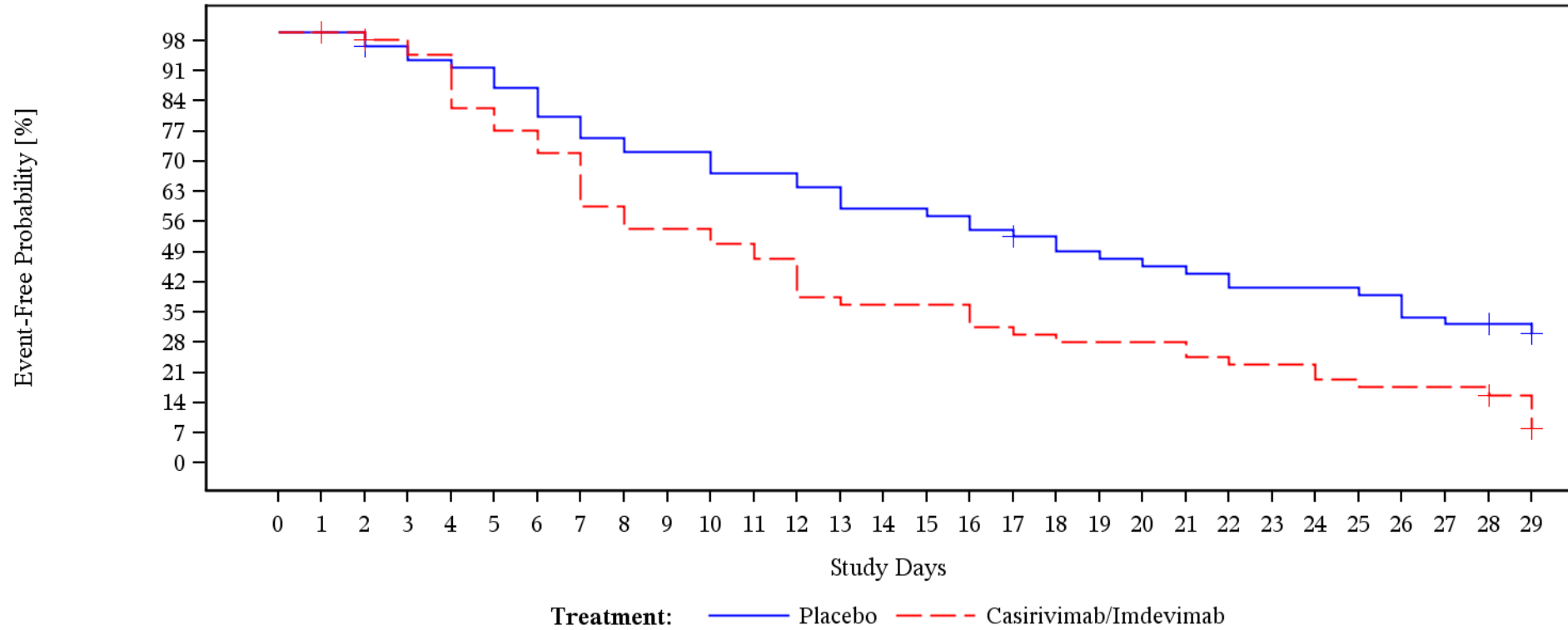
Placebo	1051	1051	637	615	589	565	532	508	486	441	400	363	340	309	288	262	246	230	213	206	189	178	172	164	153	146	136	125	111	60
Casirivimab/Imdevimab	1043	1043	658	631	597	570	528	486	457	413	364	312	290	265	234	208	195	181	170	154	146	138	130	119	109	101	96	94	80	53

Patients Censored

Placebo	0	414	418	419	420	421	424	427	427	430	430	430	432	432	432	432	433	433	434	435	437	438	440	440	442	443	444	453	499	553
Casirivimab/Imdevimab	0	385	387	388	388	390	392	394	395	396	397	397	397	398	401	401	401	401	402	402	403	403	405	409	410	411	412	418	439	480

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

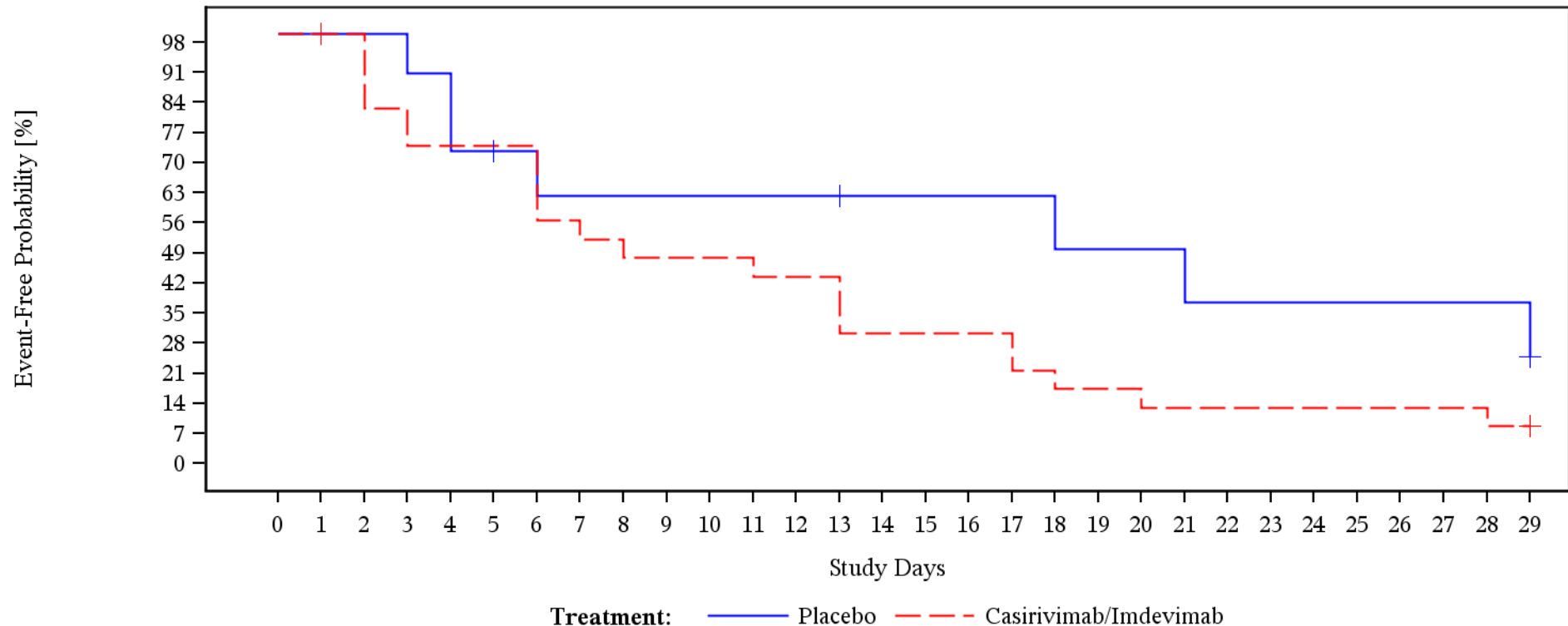
Placebo	108	108	63	59	57	56	53	49	46	44	44	41	41	39	36	36	35	33	31	29	28	27	26	24	24	24	23	20	19	16
Casirivimab/Imdevimab	100	100	58	56	54	47	44	41	34	31	31	29	27	22	21	21	21	18	17	16	16	16	14	13	13	11	10	10	10	4

Patients Censored

Placebo	0	45	47	47	47	47	47	47	47	47	47	47	47	47	47	47	47	48	48	48	48	48	48	48	48	48	48	48	48	51	66
Casirivimab/Imdevimab	0	42	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	48	50

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

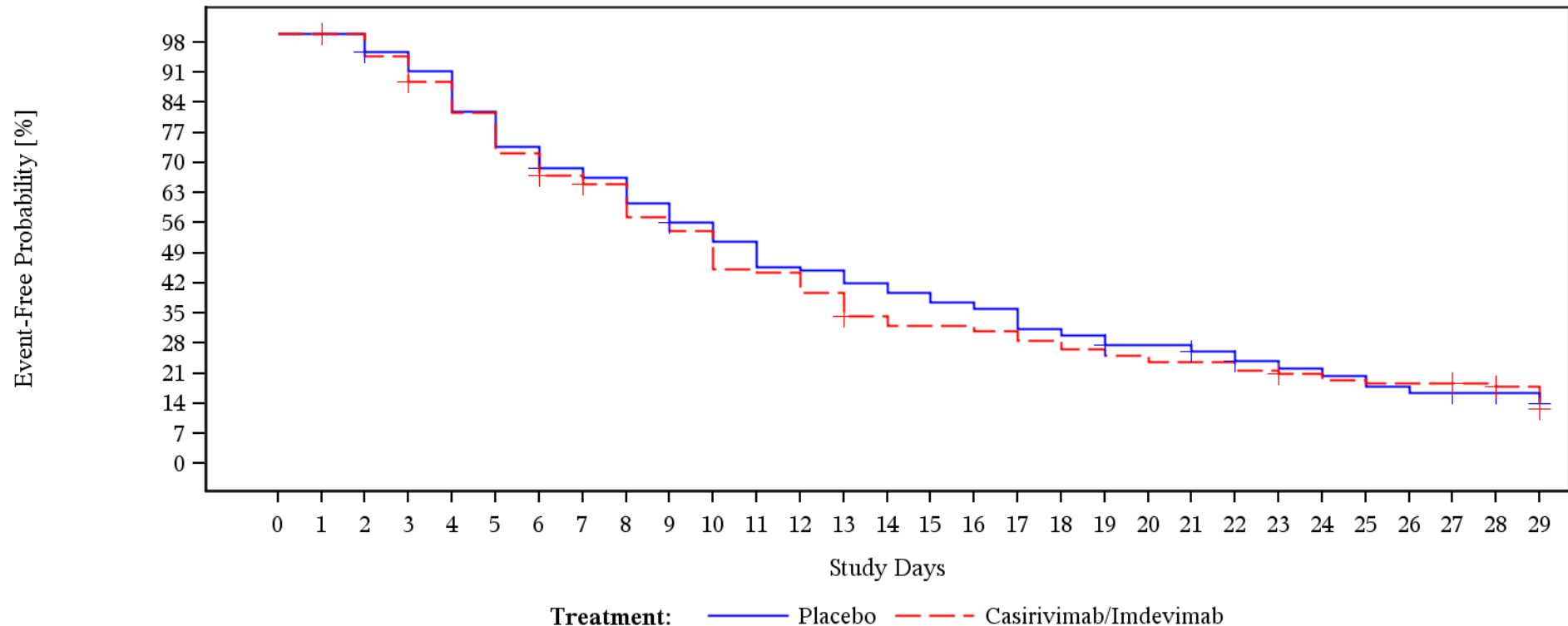
Placebo	34	34	11	11	10	8	7	6	6	6	6	6	6	5	5	5	5	5	4	4	4	3	3	3	3	3	3	3
Casirivimab/Imdevimab	49	49	23	19	17	17	13	12	11	11	11	10	10	7	7	7	7	5	4	4	3	3	3	3	3	3	3	2

Patients Censored

Placebo	0	23	23	23	23	24	24	24	24	24	24	24	24	25	25	25	25	25	25	25	25	25	25	25	25	25	25	27
Casirivimab/Imdevimab	0	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	28

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

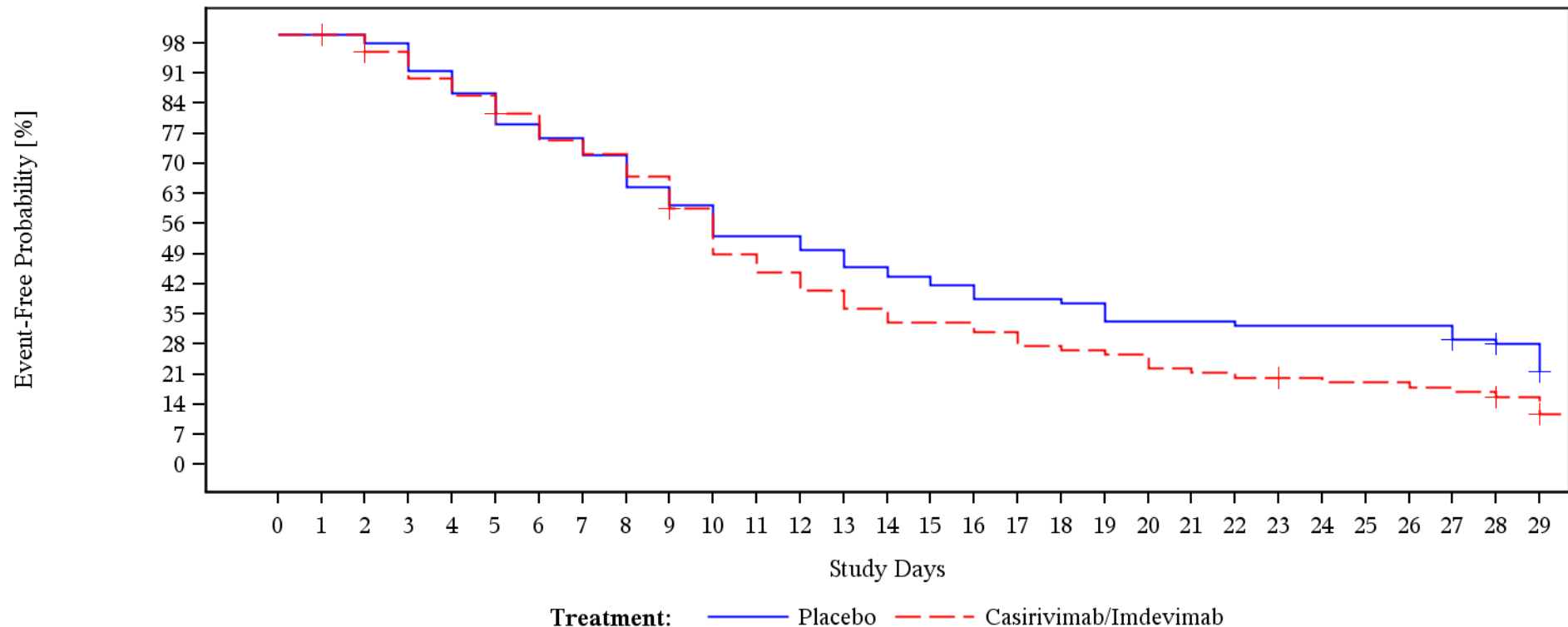
Placebo	242	242	138	131	125	112	101	93	90	82	75	69	61	60	56	53	50	48	42	40	36	36	33	29	27	25	22	20	19	14
Casirivimab/Imdevimab	260	260	152	144	134	123	109	100	95	84	79	66	65	58	49	46	46	44	41	38	36	34	34	31	29	27	26	26	24	17

Patients Censored

Placebo	0	104	105	105	105	105	106	106	106	107	107	107	107	107	107	107	107	107	107	108	108	109	110	110	110	110	110	111	116	128
Casirivimab/Imdevimab	0	108	108	109	109	109	110	112	112	112	112	112	112	113	113	113	113	113	113	113	113	113	113	114	114	114	114	116	122	134

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

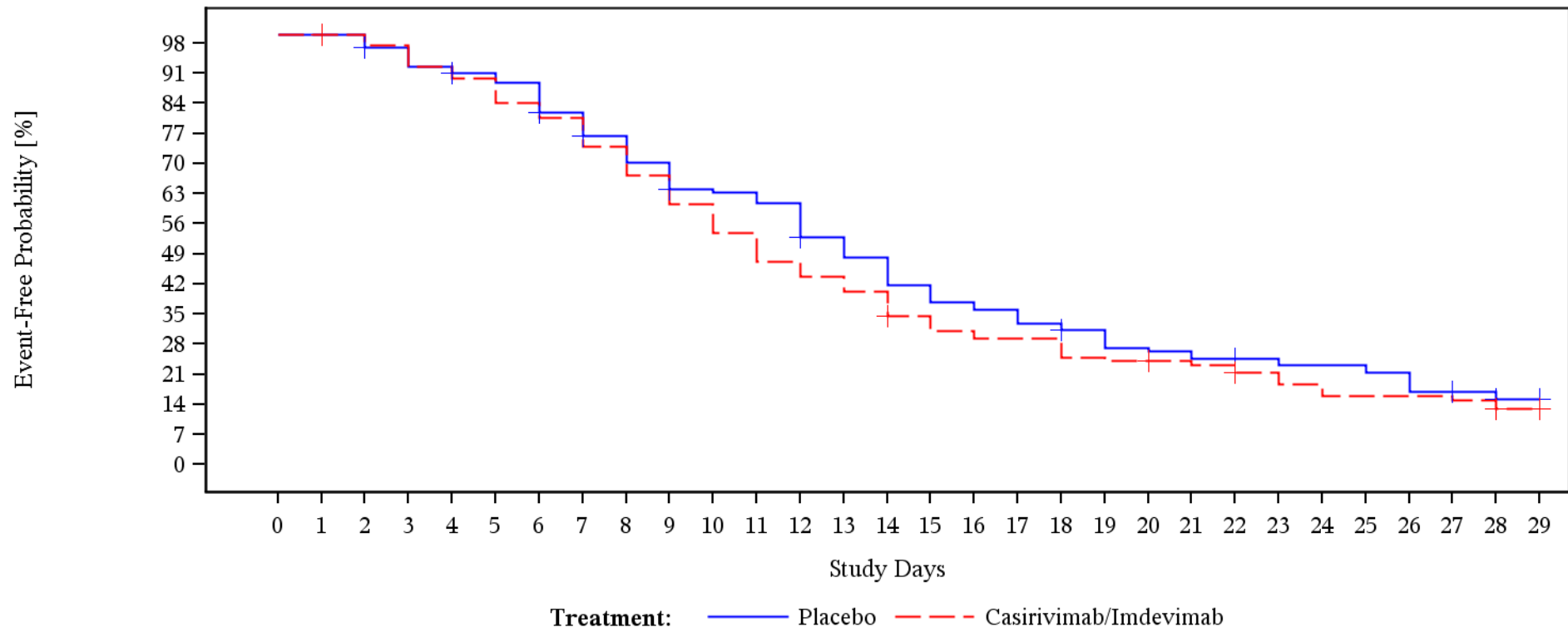
Placebo	183	183	96	94	88	83	76	73	69	62	58	51	51	48	44	42	40	37	37	36	32	32	32	31	31	31	31	31	27	13
Casirivimab/Imdevimab	158	158	99	94	88	84	78	72	69	64	56	46	42	38	34	31	31	29	26	25	24	21	20	19	18	17	17	16	15	12

Patients Censored

Placebo	0	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	87	88	101	111
Casirivimab/Imdevimab	0	59	60	60	60	62	62	62	62	63	63	63	63	63	63	63	63	63	63	63	63	63	63	63	64	64	64	64	64	66	74

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

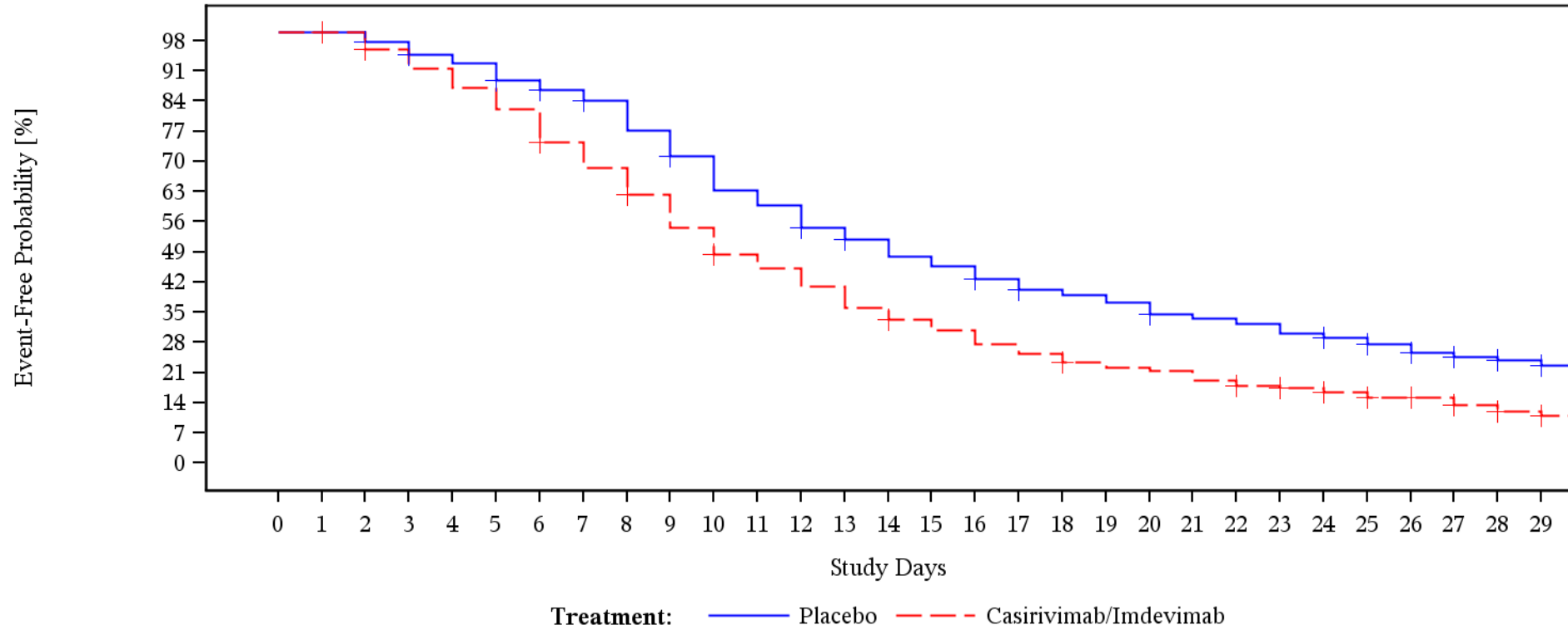
Placebo	205	205	134	129	123	120	117	107	98	90	81	80	77	66	60	52	47	45	41	38	33	32	30	29	27	27	25	20	19	10
Casirivimab/Imdevimab	183	183	119	116	110	107	100	96	88	80	72	64	56	52	48	40	36	34	34	29	28	27	26	23	20	17	17	17	16	8

Patients Censored

Placebo	0	71	72	72	73	73	74	76	76	77	77	77	78	78	78	78	78	78	79	79	79	79	80	80	80	80	80	81	88	98	
Casirivimab/Imdevimab	0	64	64	64	64	64	64	64	64	64	64	64	64	64	65	65	65	65	65	65	65	66	66	67	67	67	67	67	67	73	81

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

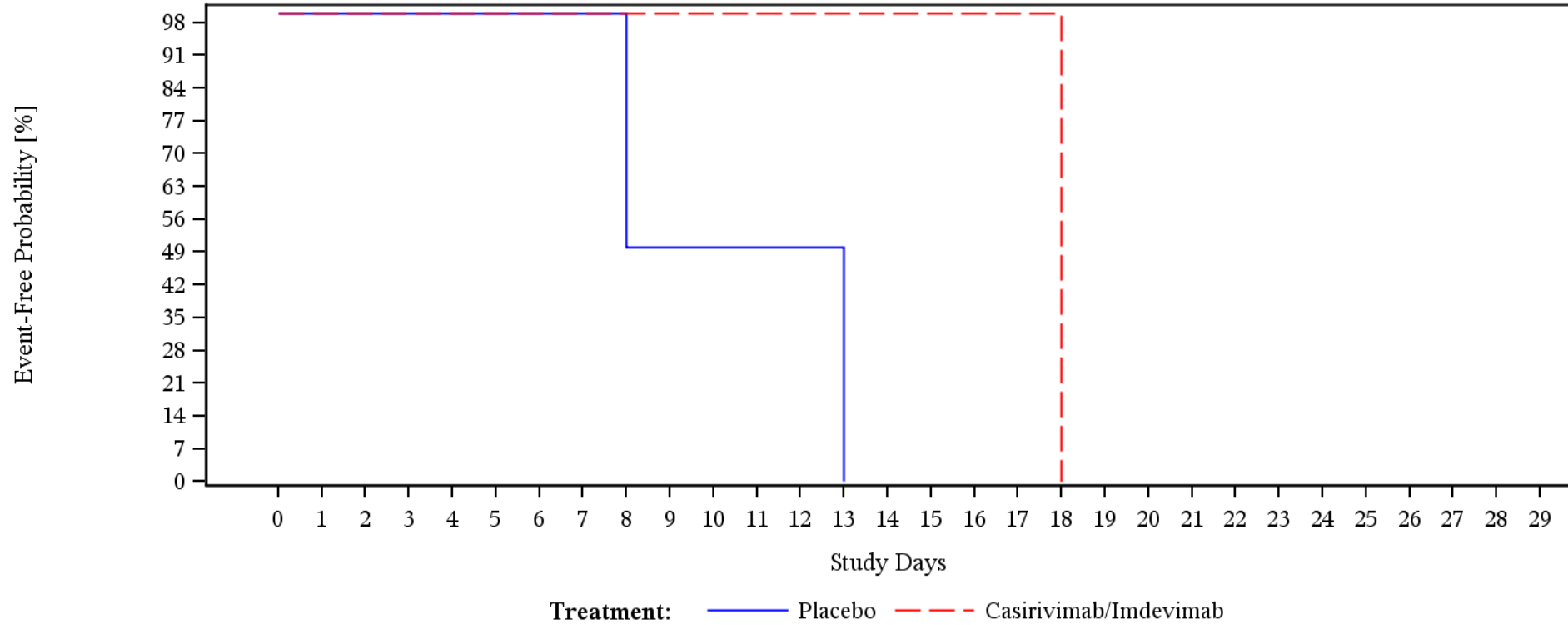
Placebo	561	561	341	329	318	312	296	288	279	256	235	209	197	179	169	156	149	138	129	125	120	109	106	102	95	90	84	77	68	42
Casirivimab/Imdevimab	590	590	368	351	335	319	301	271	250	226	198	175	163	148	130	118	109	98	90	82	78	75	67	62	58	54	49	48	38	22

Patients Censored

Placebo	0	220	224	225	225	227	228	229	229	230	230	230	231	232	232	232	233	234	234	234	236	236	236	236	238	239	240	246	270	309
Casirivimab/Imdevimab	0	222	224	224	224	224	225	225	226	226	227	227	227	227	229	229	229	229	230	230	230	230	231	233	234	235	236	240	252	269

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=Unknown



Patients At Risk

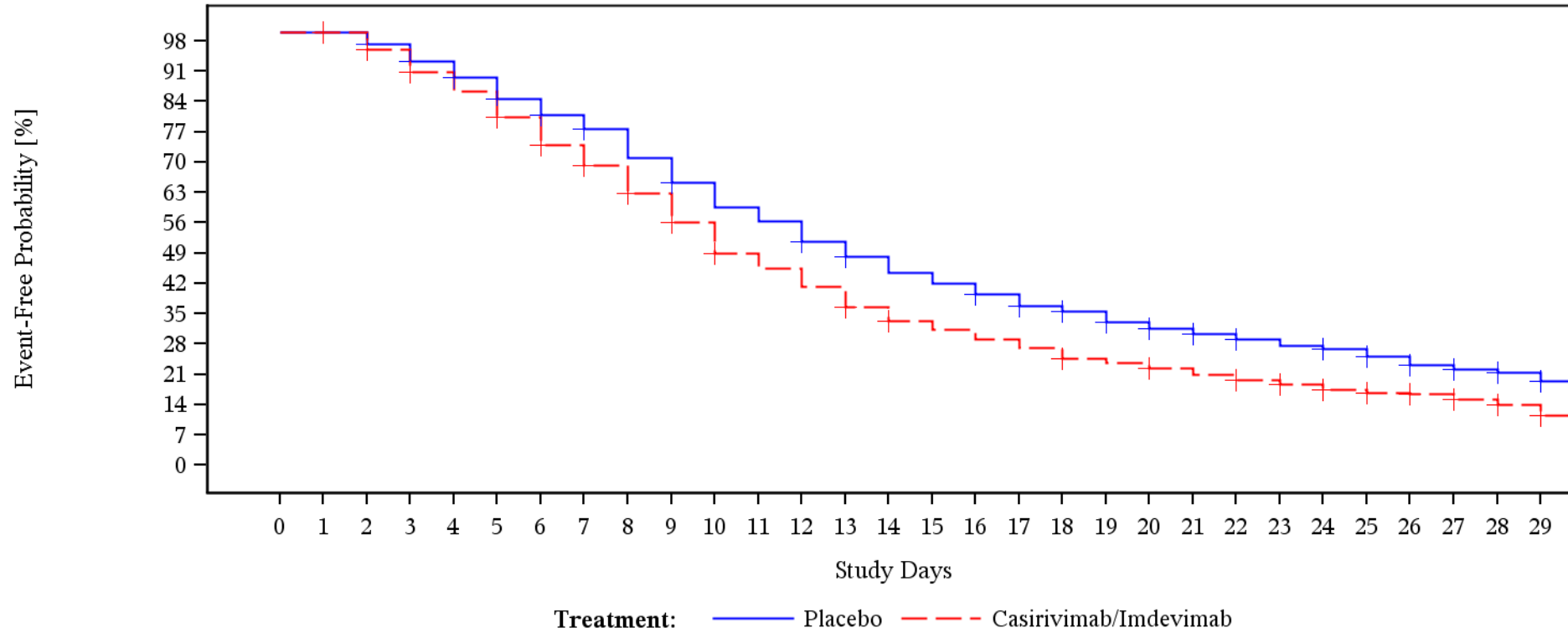
Placebo	2	2	2	2	2	2	2	2	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

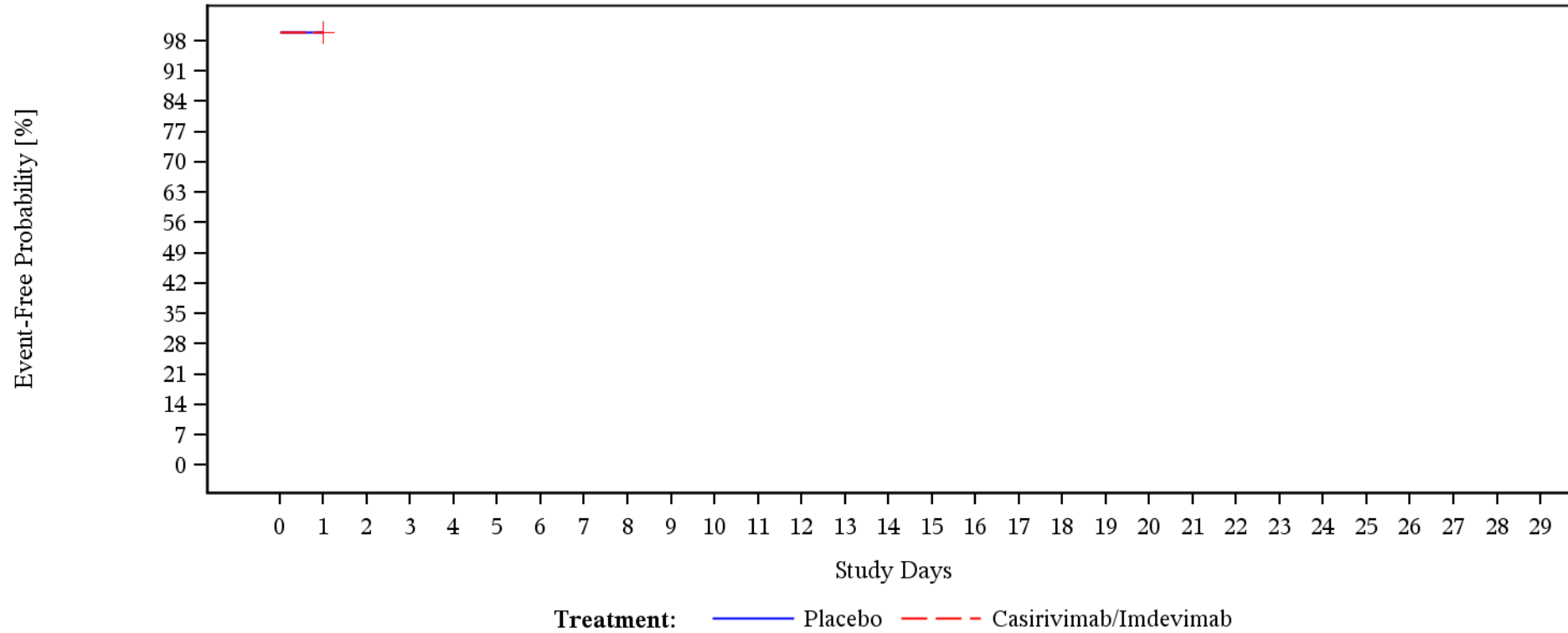
Placebo	1112	1112	711	685	656	629	592	563	538	491	450	410	387	354	329	303	286	268	249	239	221	209	201	191	180	173	162	148	133	79
Casirivimab/Imdevimab	1116	1116	739	706	668	634	589	540	503	455	406	352	327	297	262	236	223	206	192	174	166	157	147	135	125	115	109	107	93	59

Patients Censored

Placebo	0	401	407	408	409	411	414	417	417	420	420	420	422	423	423	423	424	425	426	427	429	430	432	432	434	435	436	445	494	565	
Casirivimab/Imdevimab	0	377	380	381	381	383	385	387	388	389	390	390	390	391	394	394	394	394	394	395	395	396	396	398	402	403	404	405	411	437	482

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Country=MEX



Patients At Risk

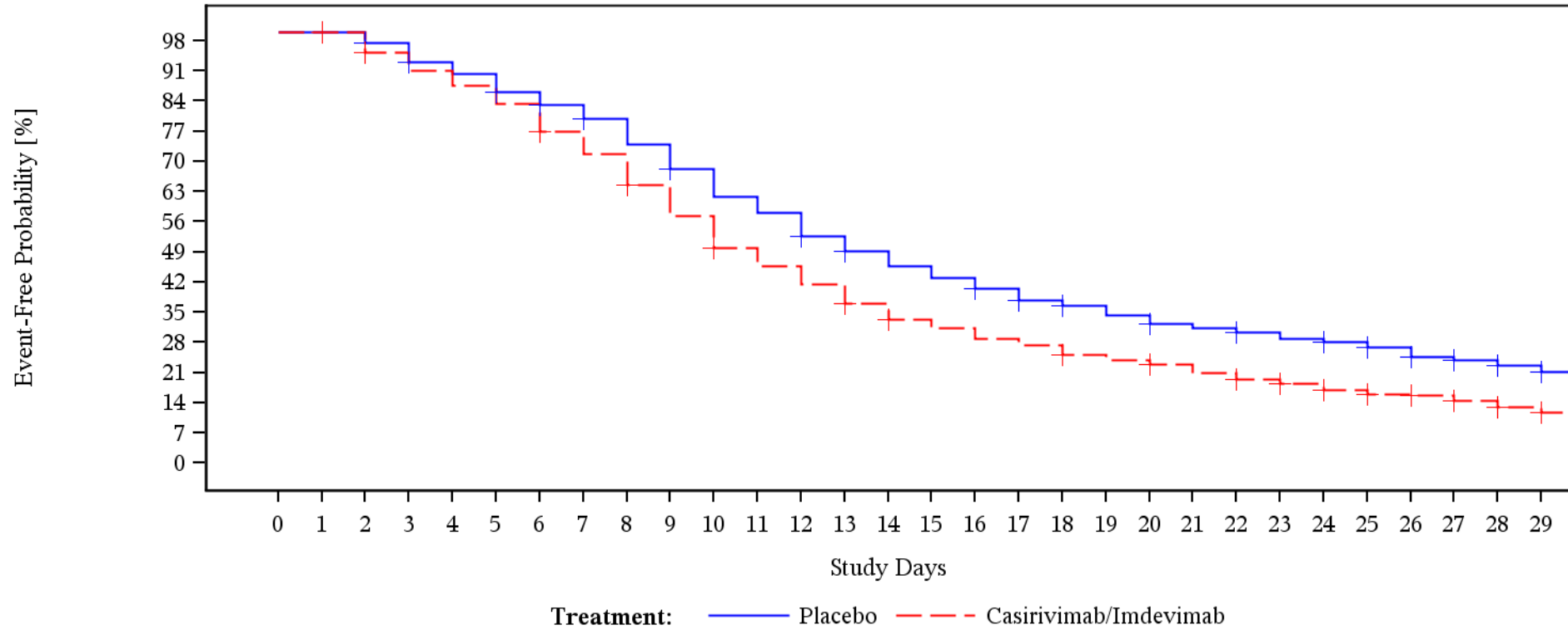
Placebo	81	81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	76	76	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81
Casirivimab/Imdevimab	0	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

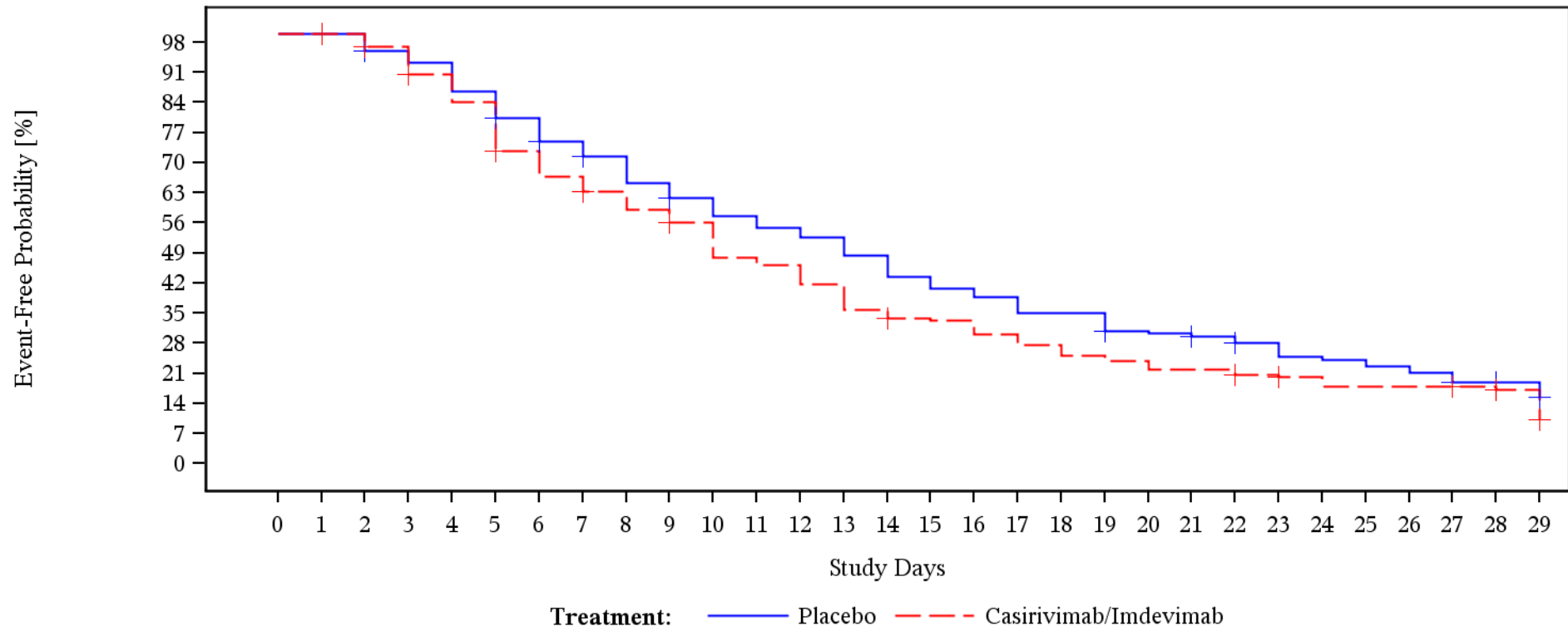
Placebo	813	813	507	492	469	455	433	416	398	368	338	306	288	259	241	223	210	197	183	176	165	154	149	143	136	131	124	112	101	60
Casirivimab/Imdevimab	798	798	506	480	459	441	420	386	360	323	286	248	227	206	183	163	153	141	134	122	116	110	100	92	85	78	72	70	62	39

Patients Censored

Placebo	0	306	308	309	309	310	312	314	314	316	316	316	318	319	319	319	320	321	322	322	324	324	325	325	327	328	329	337	373	428
Casirivimab/Imdevimab	0	292	294	294	294	294	296	296	297	297	298	298	298	299	301	301	301	301	302	302	303	303	304	306	307	308	309	311	328	360

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

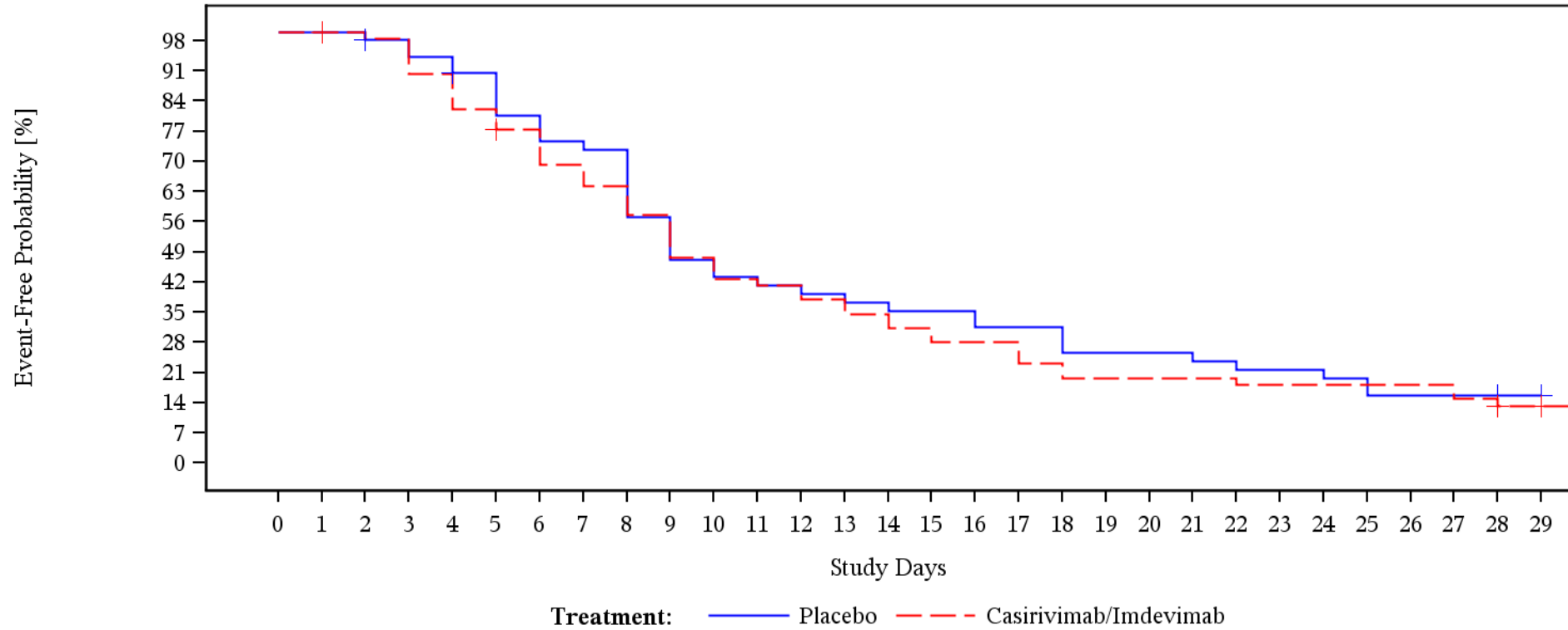
Placebo	284	284	150	142	138	128	118	109	103	94	88	82	78	75	69	62	58	55	50	50	43	42	40	37	33	32	30	28	24	16
Casirivimab/Imdevimab	311	311	171	165	153	142	122	112	104	97	91	78	75	68	58	54	53	48	44	40	38	35	35	32	29	26	26	26	22	15

Patients Censored

Placebo	0	134	136	136	136	137	138	139	139	140	140	140	140	140	140	140	140	140	140	141	141	142	143	143	143	143	143	144	152	165
Casirivimab/Imdevimab	0	140	141	142	142	143	143	145	145	146	146	146	146	146	147	147	147	147	147	147	147	147	148	150	150	150	150	154	160	169

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual health: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	96	96	54	51	49	46	41	38	37	29	24	22	21	20	19	18	18	16	16	13	13	13	12	11	11	10	8	8	8	3
Casirivimab/Imdevimab	83	83	62	61	56	51	47	42	39	35	29	26	25	23	21	19	17	17	14	12	12	12	12	11	11	11	11	11	9	5

Patients Censored

Placebo	0	42	44	44	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	50	53	
Casirivimab/Imdevimab	0	21	21	21	21	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	25	29

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-8-km-plot-subgrp-ttrtuh.pdf

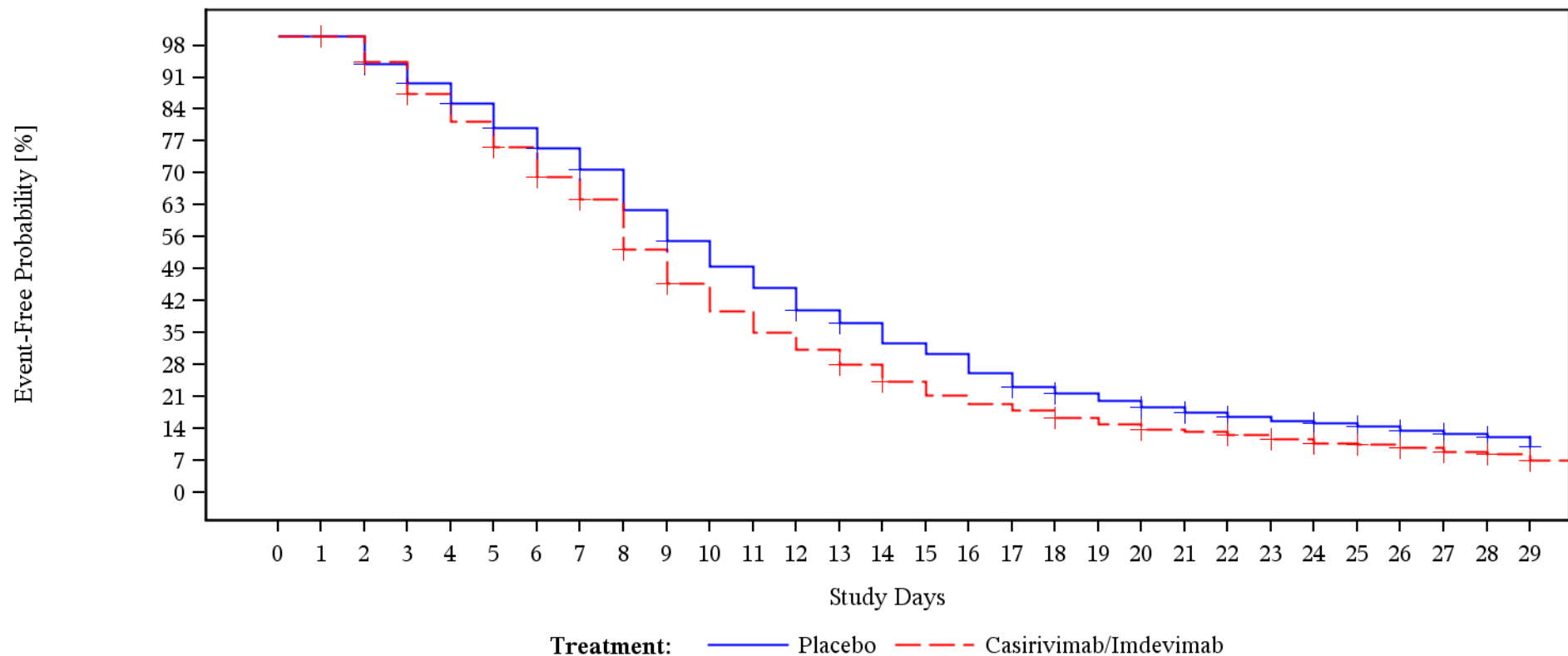
POPULATION: Modified Full Analysis Set
 ENDPOINT: Return to usual health: Time to 'Yes'
 Model: Unstratified analysis
 STUDY: R10933-10887-COV-2067
 Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab														Placebo														log-rank p-value	Hazard Ratio			Interaction Test p-value (Wald ratio)
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Hazard Ratio	95% Lower CI	95% Upper CI	Convergence Status					
		n	%	n	%	n	%	95% Lower CI for Q1 (days)	95% Upper CI for Q1 (days)	Median (days)	95% Lower CI for Median	95% Upper CI for Median	n	%	n	%	n	%	95% Lower CI for Q1 (days)	95% Upper CI for Q1 (days)	Median (days)	95% Lower CI for Median	95% Upper CI for Median											
All	n/a	1192	100	633	53.104	559	46.896	6	6	7	10	10	11	1193	100	547	45.851	546	54.149	8	7	8	13	12	14	<.0001	1.316	1.173	1.476	Convergence criterion (GCONV=1E-8) satisfied.				
Sex	Male	579	48.574	324	55.959	255	44.041	6	5	7	10	9	10	580	48.617	270	46.552	310	53.448	8	7	9	13	12	14	<.0001	1.415	1.203	1.684	Convergence criterion (GCONV=1E-8) satisfied.	0.256			
	Female	613	51.426	309	50.408	304	49.592	7	6	8	12	10	13	613	51.383	277	45.188	336	54.812	8	7	8	13	12	14	0.01	1.229	1.045	1.446	Convergence criterion (GCONV=1E-8) satisfied.				
Age	18-64	1043	87.5	562	53.883	481	46.117	6	6	7	10	10	11	1051	88.997	498	47.383	553	52.617	8	7	8	13	12	14	<.0001	1.268	1.123	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.2063			
	65-74	100	8.389	50	50	50	50	6	4	7	11	7	13	108	9.053	42	38.889	66	61.111	8	6	12	18	13	26	0.0055	1.756	1.16	2.657	Convergence criterion (GCONV=1E-8) satisfied.				
	>=75	49	4.111	21	42.857	28	57.143	3	2	6	6	6	13	34	2.85	7	20.588	27	79.412	4	3	21	18	4	NE	0.1249	1.898	0.797	4.518	Convergence criterion (GCONV=1E-8) satisfied.				
Baseline viral load categories	<=10^6 copies/mL	300	21.812	126	42.02	134	44.68	5	4	6	10	8	12	242	20.285	114	47.107	128	52.893	5	4	7	11	9	14	0.6475	1.058	0.821	1.364	Convergence criterion (GCONV=1E-8) satisfied.	0.0977			
	>10^6 copies/mL - <=10^7 copies/mL	158	13.265	84	53.165	74	46.835	7	5	9	10	9	13	183	15.339	72	39.344	111	60.656	7	5	8	12.5	9	16	0.0969	1.292	0.941	1.774	Convergence criterion (GCONV=1E-8) satisfied.				
	>10^7 copies/mL - <=10^8 copies/mL	183	15.352	102	55.738	81	44.262	7	6	8	11	10	13	205	17.184	107	52.195	98	47.805	8	6	9	13	12	15	0.2989	1.149	0.876	1.507	Convergence criterion (GCONV=1E-8) satisfied.				
	>10^8 copies/mL	590	49.497	320	54.237	270	45.763	6	6	7	10	9	12	561	47.024	252	44.92	309	55.08	9	8	10	14	12	16	<.0001	1.518	1.286	1.792	Convergence criterion (GCONV=1E-8) satisfied.				
	Unknown	1	0.084	1	100	0	0	18	NE	NE	18	NE	NE	2	0.168	2	100	0	0	8	8	13	10.5	8	13	0.2293	0	0	NE	Convergence criterion (GCONV=1E-8) satisfied.				
Country	USA	1116	93.624	633	56.72	483	43.28	6	6	7	10	10	11	1112	93.21	547	49.191	565	50.809	8	7	8	13	12	14	<.0001	1.316	1.173	1.476	Convergence criterion (GCONV=1E-8) satisfied.				
	MEX	76	6.376	0	0	76	100	NE	NE	NE	NE	NE	NE	81	6.79	0	0	81	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Baseline serostatus	Negative	798	66.946	437	54.762	361	45.238	7	6	8	10	10	11	813	68.148	385	47.365	428	52.645	8	8	9	13	12	14	<.0001	1.375	1.198	1.577	Convergence criterion (GCONV=1E-8) satisfied.	0.3979			
	Positive	311	26.091	142	45.659	169	54.341	5	5	6	10	9	12	284	23.806	119	41.901	165	58.099	6	5	8	13	10	15	0.1202	1.204	0.944	1.537	Convergence criterion (GCONV=1E-8) satisfied.				
	Other	83	6.963	54	65.06	29	34.94	6	4	7	9	8	12	96	8.047	43	44.792	53	55.208	6	5	8	9	8	14	0.6067	1.106	0.74	1.655	Convergence criterion (GCONV=1E-8) satisfied.				

Test for interaction based on Likelihood Ratio test for interaction with treatment effect.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18Aug2021.

Program t-efr-ss.sas
 Output: t13-8-efr-ss-TRTLM4

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067



Patients At Risk

Placebo	1193	1193	708	660	630	597	558	523	488	427	377	338	306	272	252	222	206	177	156	145	135	123	115	108	101	97	92	85	77	48
Casirivimab/Imdevimab	1192	1192	727	682	631	586	545	495	458	379	325	281	249	222	198	169	148	135	126	113	102	93	90	82	73	64	62	57	50	30

Patients Censored

Placebo	0	485	490	491	492	494	497	501	501	504	504	504	505	506	506	506	506	507	508	508	510	511	512	512	513	514	515	519	543	583
Casirivimab/Imdevimab	0	465	469	470	470	472	474	476	477	478	478	478	478	479	481	481	481	481	483	483	485	485	488	491	494	495	496	497	515	539

Showing data observed through Day 29

Clinical cutoff: 19AUG2021

Program: f-km-plot.sas

Output: fl-9-km-plot-ttrtua.pdf

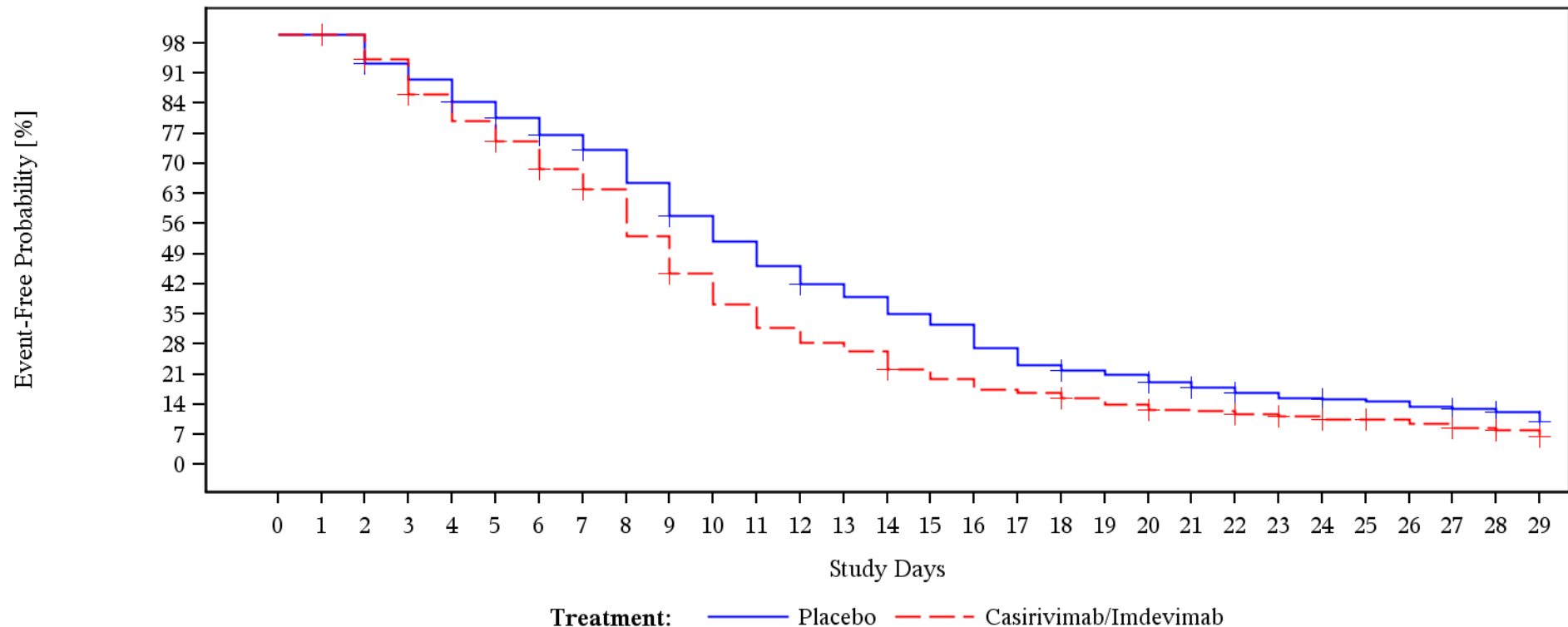
POPULATION: Modified Full Analysis Set
ENDPOINT: Return to usual activities: Time to 'Yes'
Model: Stratified analysis
STUDY: R10933-10987-COV-2067
Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab										Placebo						Casirivimab/Imdevimab vs. Placebo														
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status		
All	n/a	1192	100	652	54,698	540	45,302	6	5	6	9	8	9	1193	100	610	51,132	583	48,868	7	6	7	10	10	11	0,0003	1,213	1,086	1,354	Convergence criterion (GCONV=1E-8) satisfied.		

Stratification factor = Country.
 Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
 * indicates convergence problem. Result is uninterpretable
 Clinical cut-off: 19Aug2021.

Program: t-eff-tte.sas
 Output: t13-9-eff-tte-TTRTUA

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Male



Patients At Risk

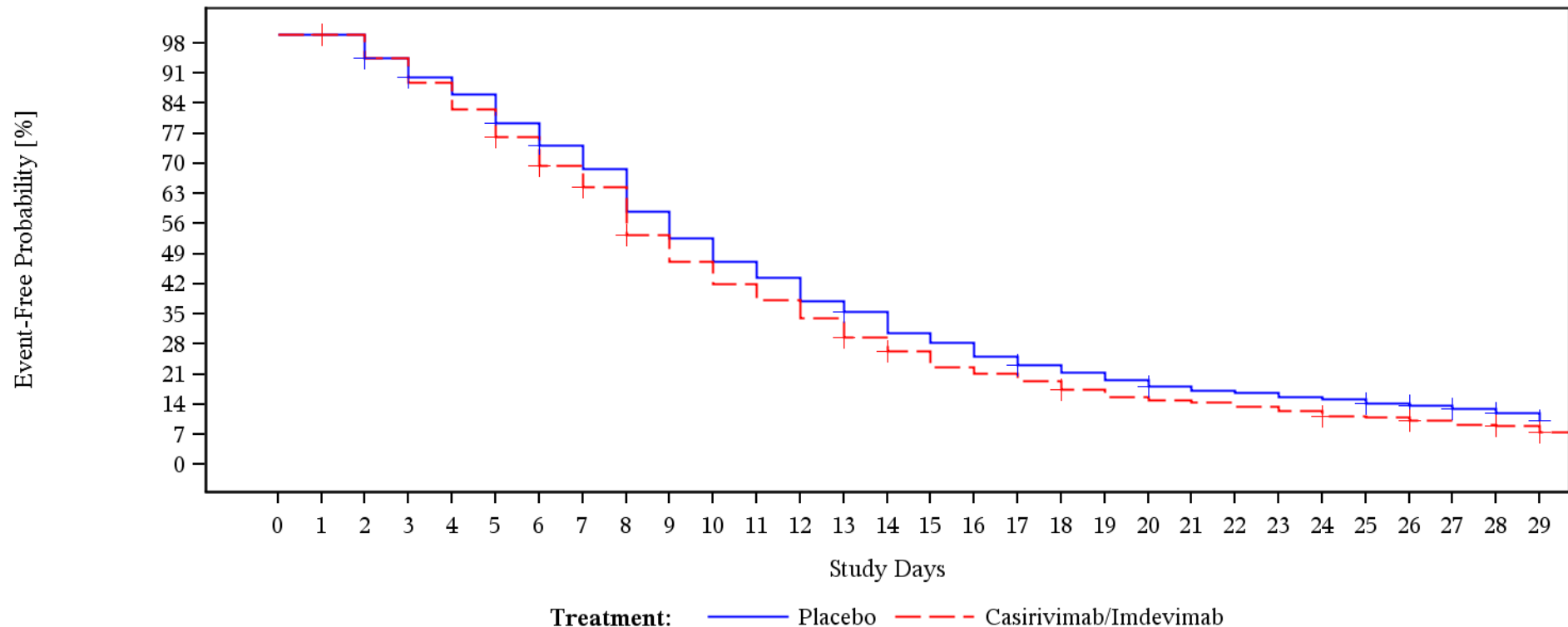
Placebo	580	580	353	326	313	294	280	264	248	222	193	173	154	139	129	116	108	90	77	72	68	62	57	52	48	46	45	41	36	23
Casirivimab/Imdevimab	579	579	360	335	305	283	266	242	224	186	155	130	111	99	92	76	68	60	57	52	47	41	40	35	30	27	26	24	20	11

Patients Censored

Placebo	0	227	230	230	231	232	234	238	238	241	241	241	242	242	242	242	242	242	243	243	244	245	246	246	247	247	247	250	261	280
Casirivimab/Imdevimab	0	219	223	224	224	225	226	227	227	228	228	228	228	228	229	229	229	229	230	230	232	232	235	238	239	240	240	241	249	258

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Sex=Female



Patients At Risk

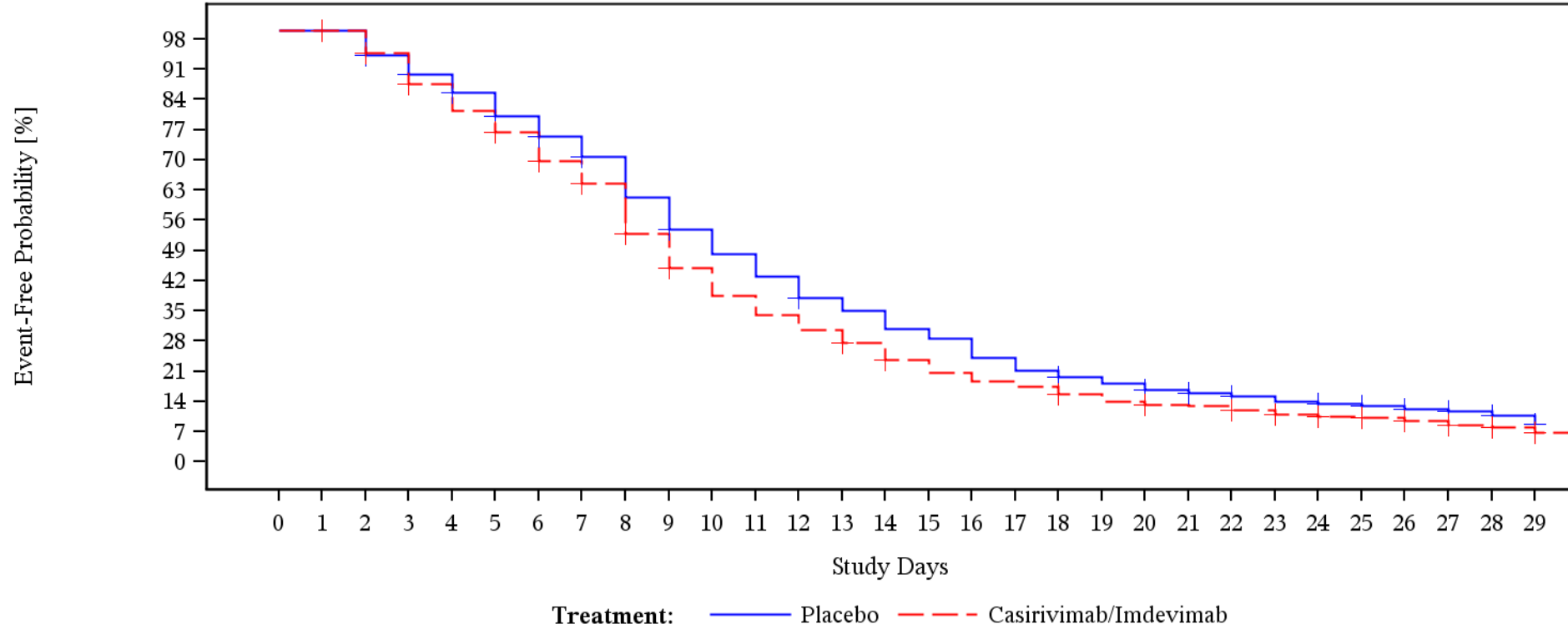
Placebo	613	613	355	334	317	303	278	259	240	205	184	165	152	133	123	106	98	87	79	73	67	61	58	56	53	51	47	44	41	25
Casirivimab/Imdevimab	613	613	367	347	326	303	279	253	234	193	170	151	138	123	106	93	80	75	69	61	55	52	50	47	43	37	36	33	30	19

Patients Censored

Placebo	0	258	260	261	261	262	263	263	263	263	263	263	264	264	264	264	265	265	265	266	266	266	266	266	266	267	268	269	282	303
Casirivimab/Imdevimab	0	246	246	246	246	247	248	249	250	250	250	250	251	252	252	252	252	253	253	253	253	253	253	253	255	255	256	256	266	281

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=18-64



Patients At Risk

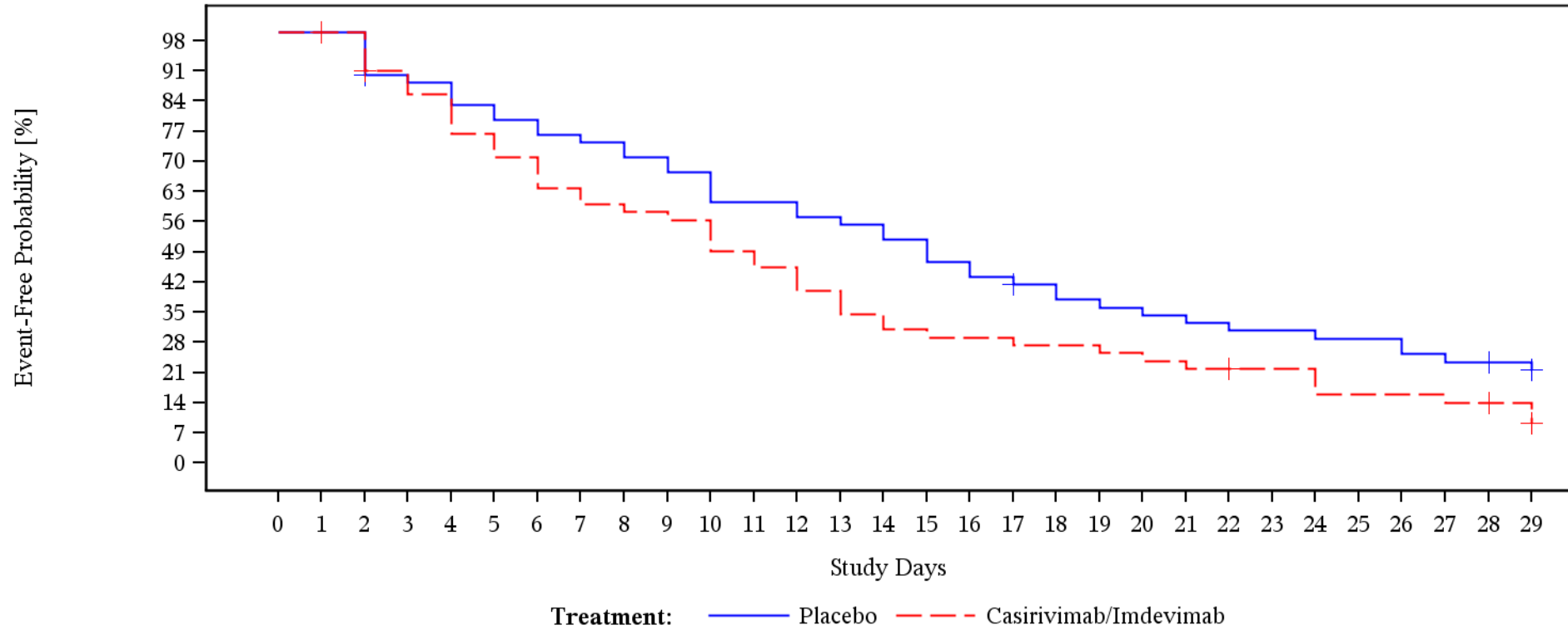
Placebo	1051	1051	637	597	569	540	505	473	439	380	332	297	265	233	215	188	175	148	129	120	111	100	94	88	81	78	73	68	61	33
Casirivimab/Imdevimab	1043	1043	649	612	565	525	490	446	411	335	284	244	215	193	173	147	128	115	108	95	85	78	76	69	60	54	52	47	41	26

Patients Censored

Placebo	0	414	417	418	419	420	423	427	427	430	430	430	431	431	431	431	431	431	432	432	434	435	436	436	437	438	439	443	466	493	
Casirivimab/Imdevimab	0	394	397	398	398	400	402	404	405	406	406	406	406	407	409	409	409	409	409	411	411	413	413	415	418	421	422	423	424	437	458

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=65-74



Patients At Risk

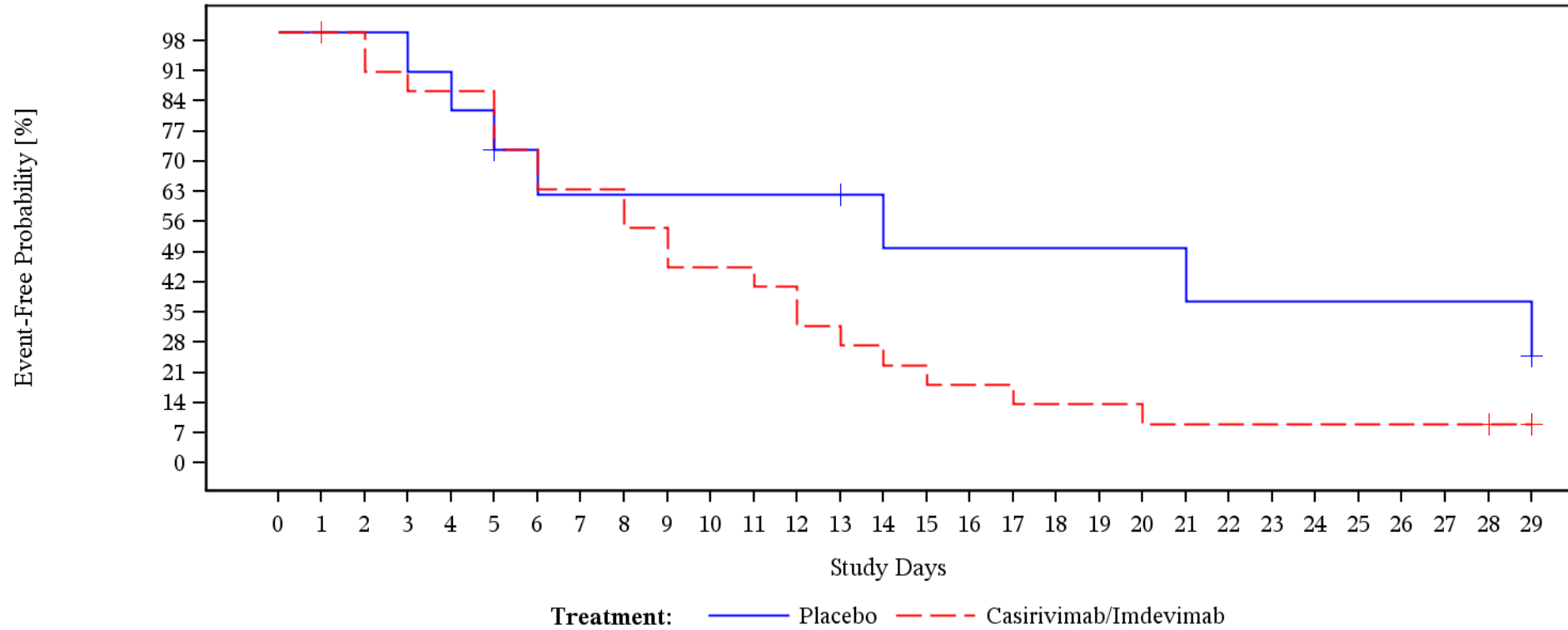
Placebo	108	108	60	52	51	48	46	44	43	41	39	35	35	33	32	30	27	25	23	21	20	19	18	17	17	16	16	14	13	12
Casirivimab/Imdevimab	100	100	56	50	47	42	39	35	33	32	31	27	25	22	19	17	16	16	15	15	14	13	12	11	11	8	8	8	7	3

Patients Censored

Placebo	0	48	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	51	51	51	51	51	51	51	51	51	51	51	51	52	63	
Casirivimab/Imdevimab	0	44	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	45	46	46	46	46	46	46	46	50	52

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Age Group=>=75



Patients At Risk

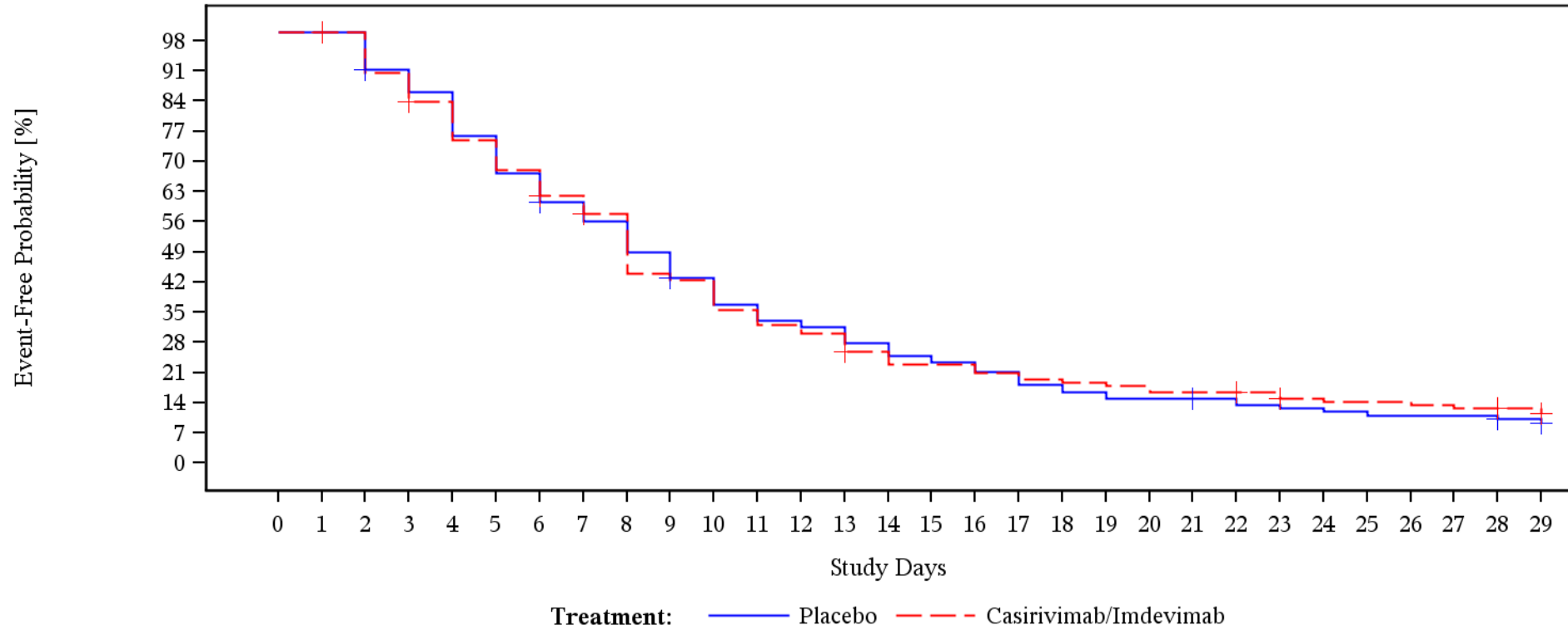
Placebo	34	34	11	11	10	9	7	6	6	6	6	6	6	5	4	4	4	4	4	4	3	3	3	3	3	3	3	
Casirivimab/Imdevimab	49	49	22	20	19	19	16	14	14	12	10	10	9	7	6	5	4	4	3	3	3	2	2	2	2	2	2	1

Patients Censored

Placebo	0	23	23	23	23	24	24	24	24	24	24	24	24	25	25	25	25	25	25	25	25	25	25	25	25	25	25	27	
Casirivimab/Imdevimab	0	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	28	29

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories= $\leq 10^5$ copies/mL



Patients At Risk

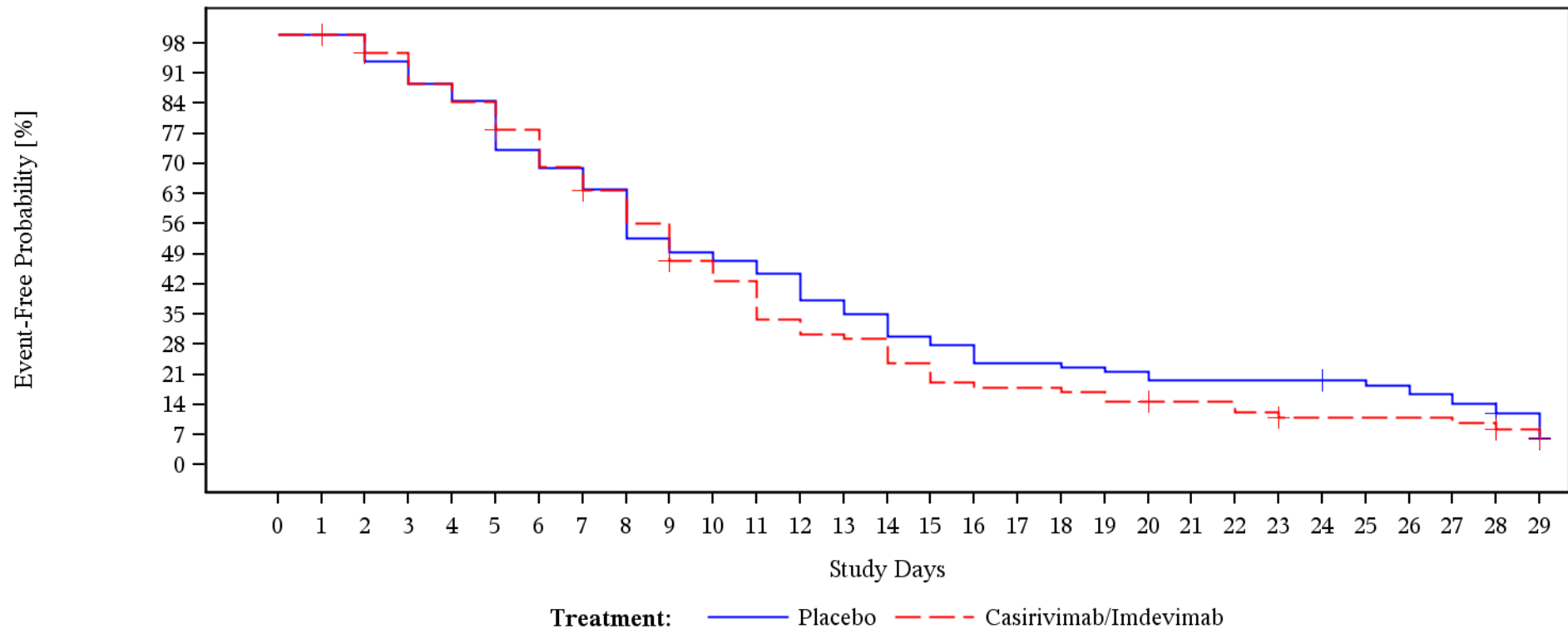
Placebo	242	242	138	125	118	104	92	82	76	66	57	49	44	42	37	33	31	28	24	22	20	20	19	17	16	15	14	14	14	10
Casirivimab/Imdevimab	260	260	148	134	123	110	100	90	83	63	61	51	46	43	36	32	32	29	27	26	25	23	23	22	19	18	18	17	16	12

Patients Censored

Placebo	0	104	105	105	105	105	106	106	106	107	107	107	107	107	107	107	107	107	107	107	107	108	108	108	108	108	108	108	108	111	120	
Casirivimab/Imdevimab	0	112	112	113	113	113	114	115	115	115	115	115	115	116	116	116	116	116	116	116	116	116	116	117	118	118	118	118	118	118	122	133

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁵ copies/mL - <=10⁶ copies/mL



Patients At Risk

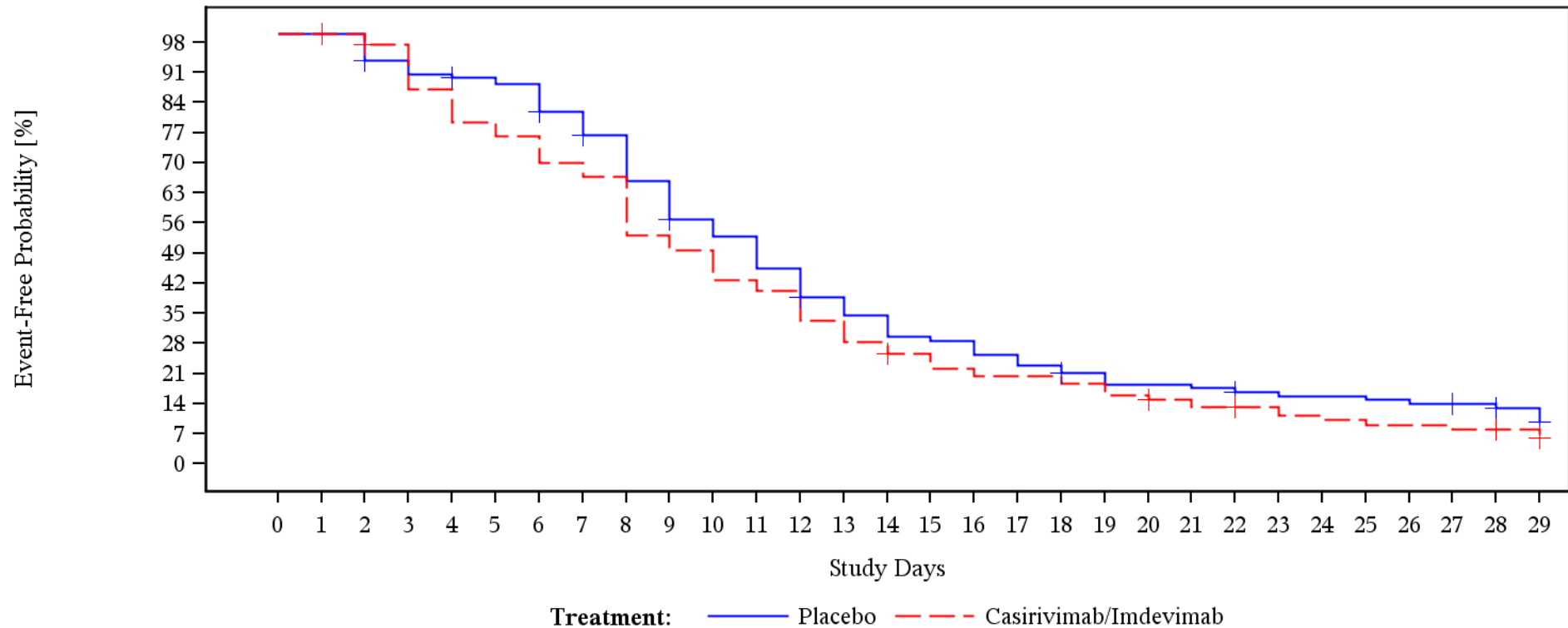
Placebo	183	183	97	91	86	82	71	67	62	51	48	46	43	37	34	29	27	23	23	22	21	19	19	19	19	18	17	15	13	6
Casirivimab/Imdevimab	158	158	96	91	84	80	72	64	58	51	42	38	30	27	26	21	17	16	16	15	13	12	12	10	8	8	8	8	7	4

Patients Censored

Placebo	0	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	86	87	87	87	87	92	95
Casirivimab/Imdevimab	0	62	63	63	63	65	65	66	66	67	67	67	67	67	67	67	67	67	67	67	68	68	68	69	69	69	69	69	71	74

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁶ copies/mL - <=10⁷ copies/mL



Patients At Risk

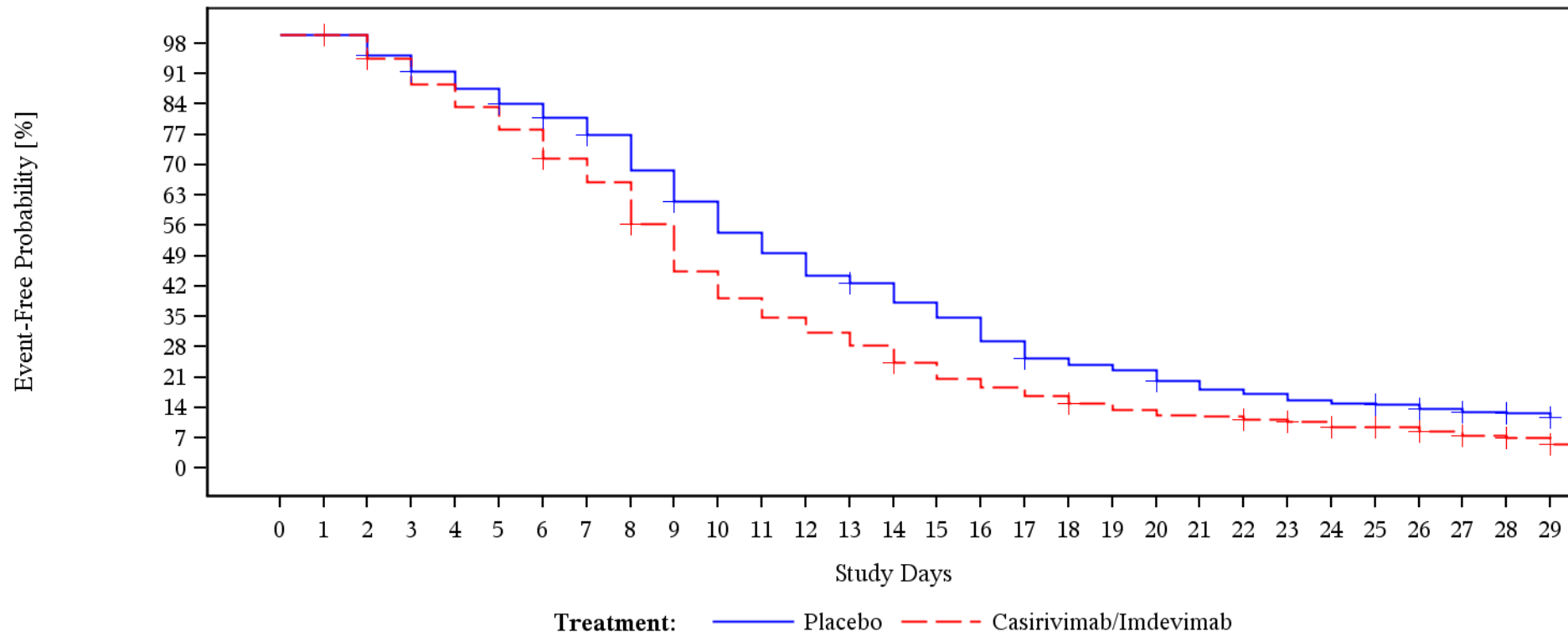
Placebo	205	205	129	120	116	114	112	103	94	81	69	64	55	46	41	35	34	30	27	24	21	21	20	18	17	17	16	15	14	8
Casirivimab/Imdevimab	183	183	118	114	102	93	89	82	78	62	58	50	47	39	33	29	25	23	23	21	18	16	14	13	11	10	9	9	8	4

Patients Censored

Placebo	0	76	77	77	78	78	79	81	81	82	82	82	83	83	83	83	83	83	84	84	84	84	85	85	85	85	85	86	91	97	
Casirivimab/Imdevimab	0	65	66	66	66	66	66	66	66	66	66	66	66	66	67	67	67	67	67	67	67	68	68	69	69	69	69	69	69	73	76

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=>10⁷ copies/mL



Patients At Risk

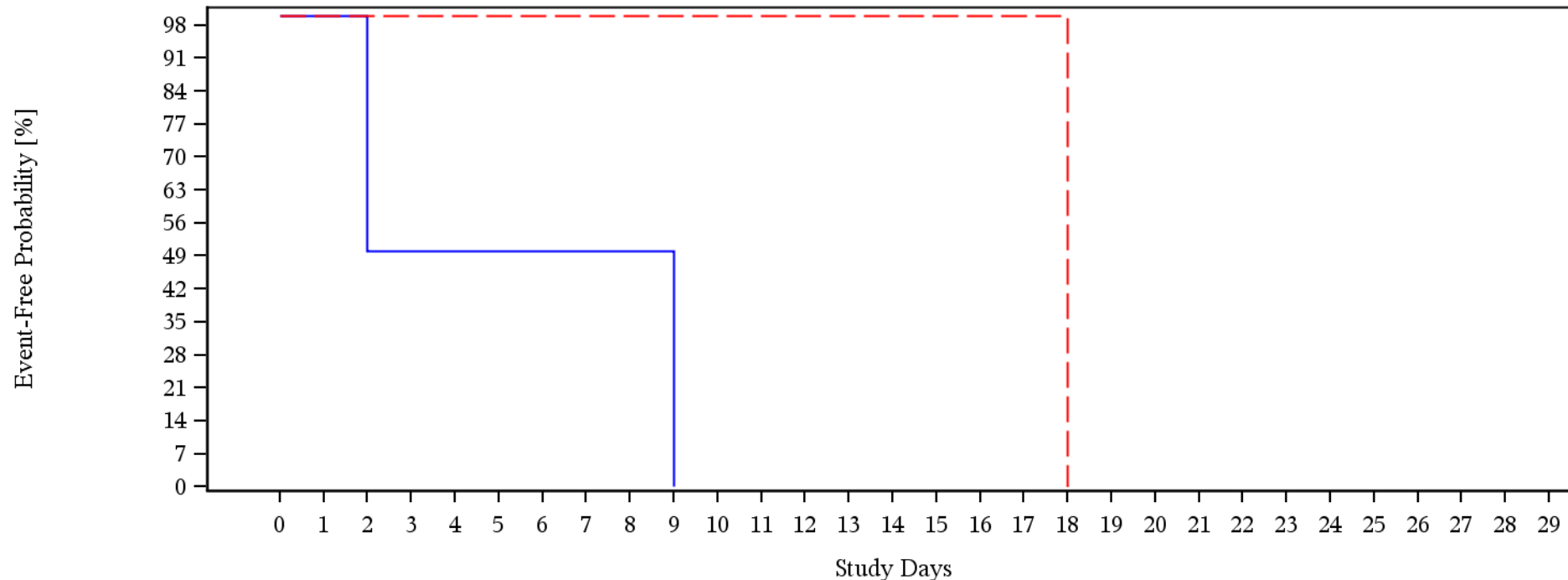
Placebo	561	561	342	323	309	296	282	270	255	228	203	179	164	147	140	125	114	96	82	77	73	63	57	54	49	47	45	41	36	24
Casirivimab/Imdevimab	590	590	364	342	321	302	283	258	238	202	163	141	125	112	102	86	73	66	59	51	46	42	41	37	35	28	27	23	19	10

Patients Censored

Placebo	0	219	222	223	223	225	226	228	228	229	229	229	229	230	230	230	230	231	231	231	233	233	233	233	233	234	235	238	249	271	
Casirivimab/Imdevimab	0	226	228	228	228	228	229	229	230	230	230	230	230	231	231	231	231	231	233	233	233	233	233	234	235	238	239	240	241	249	256

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Viral Load Categories=Unknown



Treatment: — Placebo - - - Casirivimab/Imdevimab

Patients At Risk

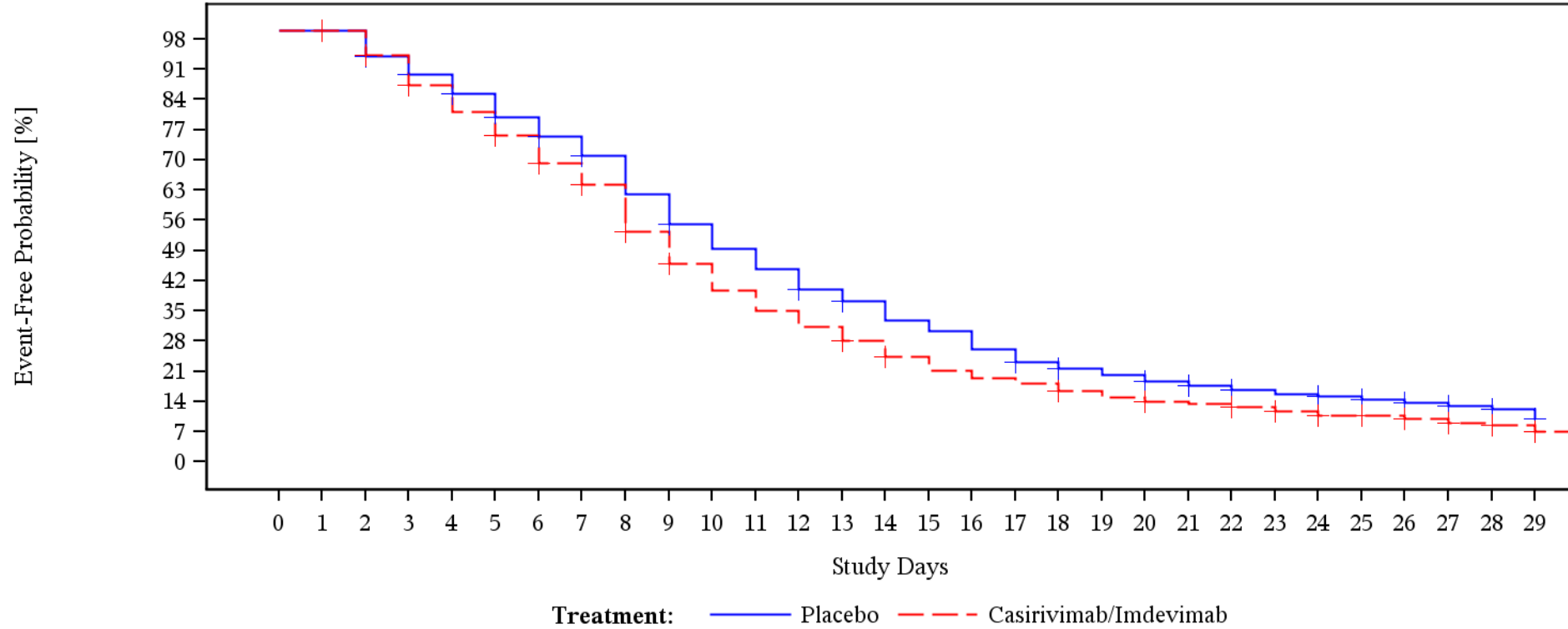
Placebo	2	2	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Patients Censored

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Country=USA



Patients At Risk

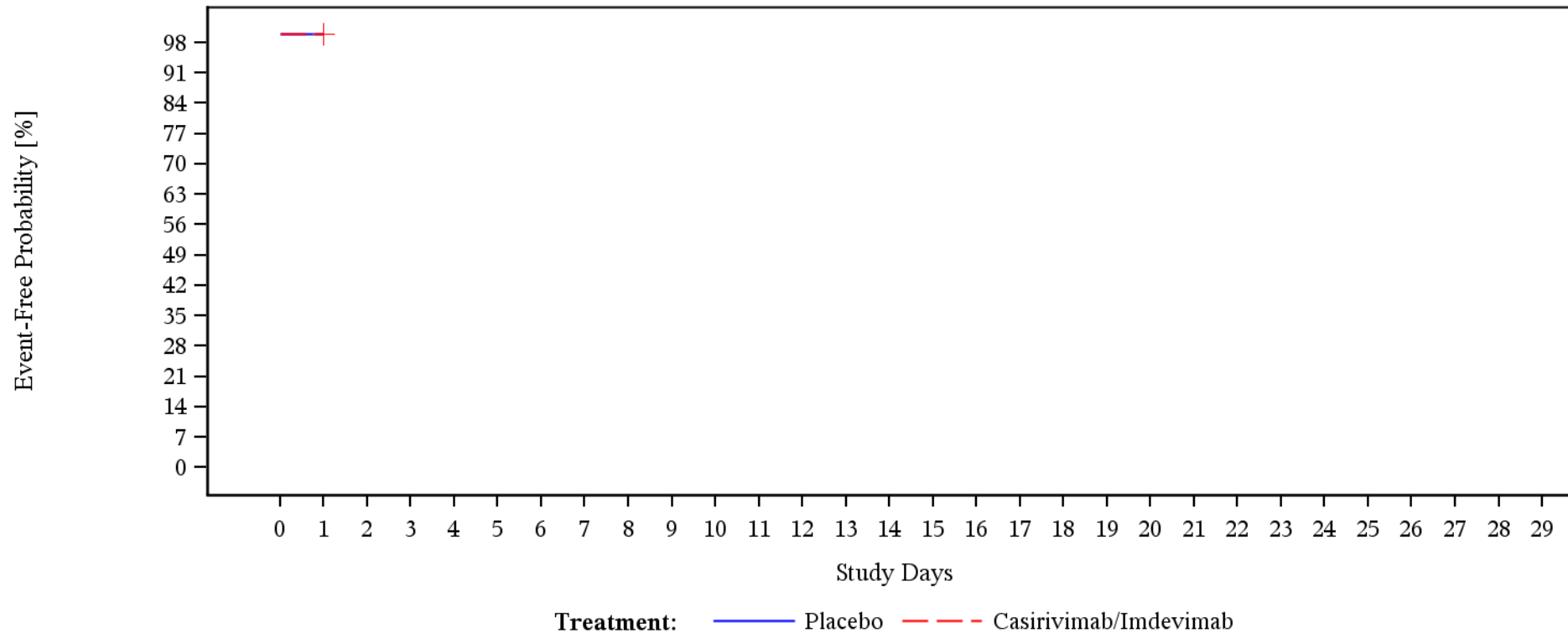
Placebo	1112	1112	708	660	630	597	558	523	488	427	377	338	306	272	252	222	206	177	156	145	135	123	115	108	101	97	92	85	77	48
Casirivimab/Imdevimab	1116	1116	727	682	631	586	545	495	458	379	325	281	249	222	198	169	148	135	126	113	102	93	90	82	73	64	62	57	50	30

Patients Censored

Placebo	0	404	409	410	411	413	416	420	420	423	423	423	424	425	425	425	425	426	427	427	429	430	431	431	432	433	434	438	462	502
Casirivimab/Imdevimab	0	389	393	394	394	396	398	400	401	402	402	402	402	403	405	405	405	405	407	407	409	409	412	415	418	419	420	421	439	463

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Country=MEX



Patients At Risk

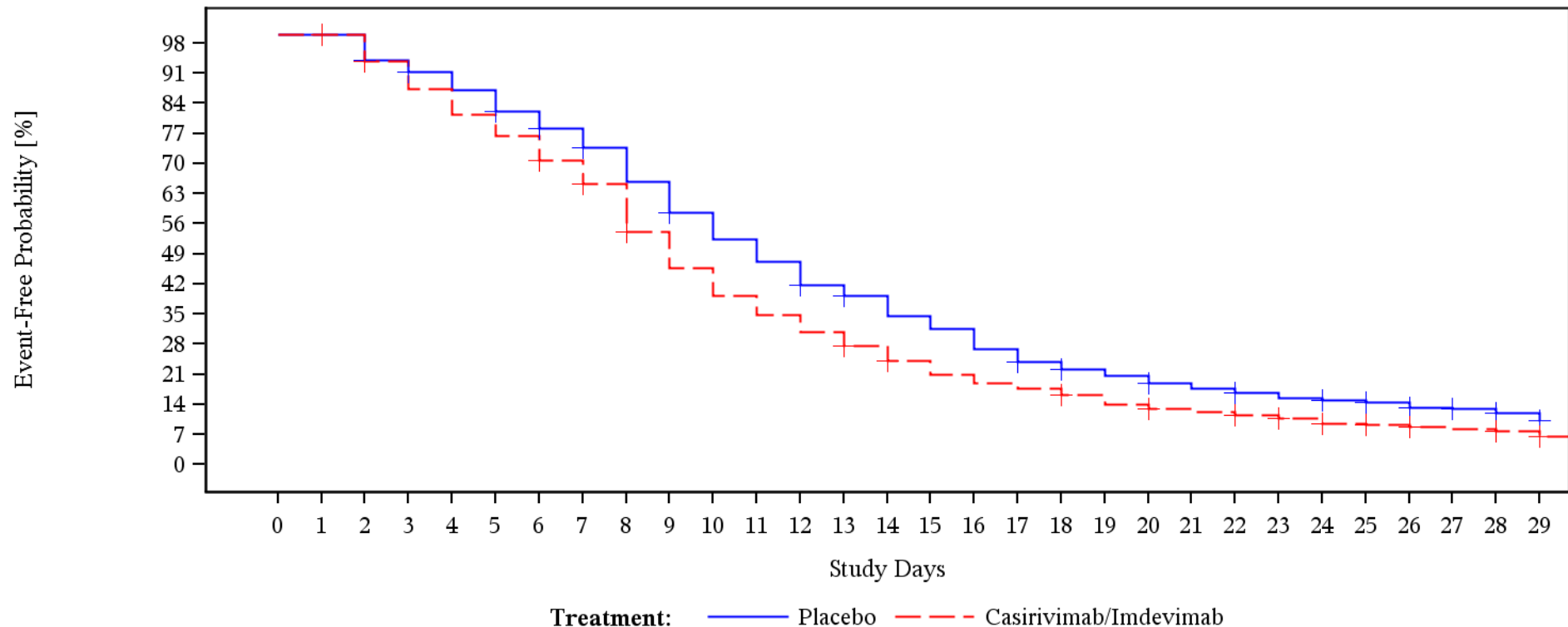
Placebo	81	81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Casirivimab/Imdevimab	76	76	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Patients Censored

Placebo	0	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81	81
Casirivimab/Imdevimab	0	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76	76

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: fl-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Negative



Patients At Risk

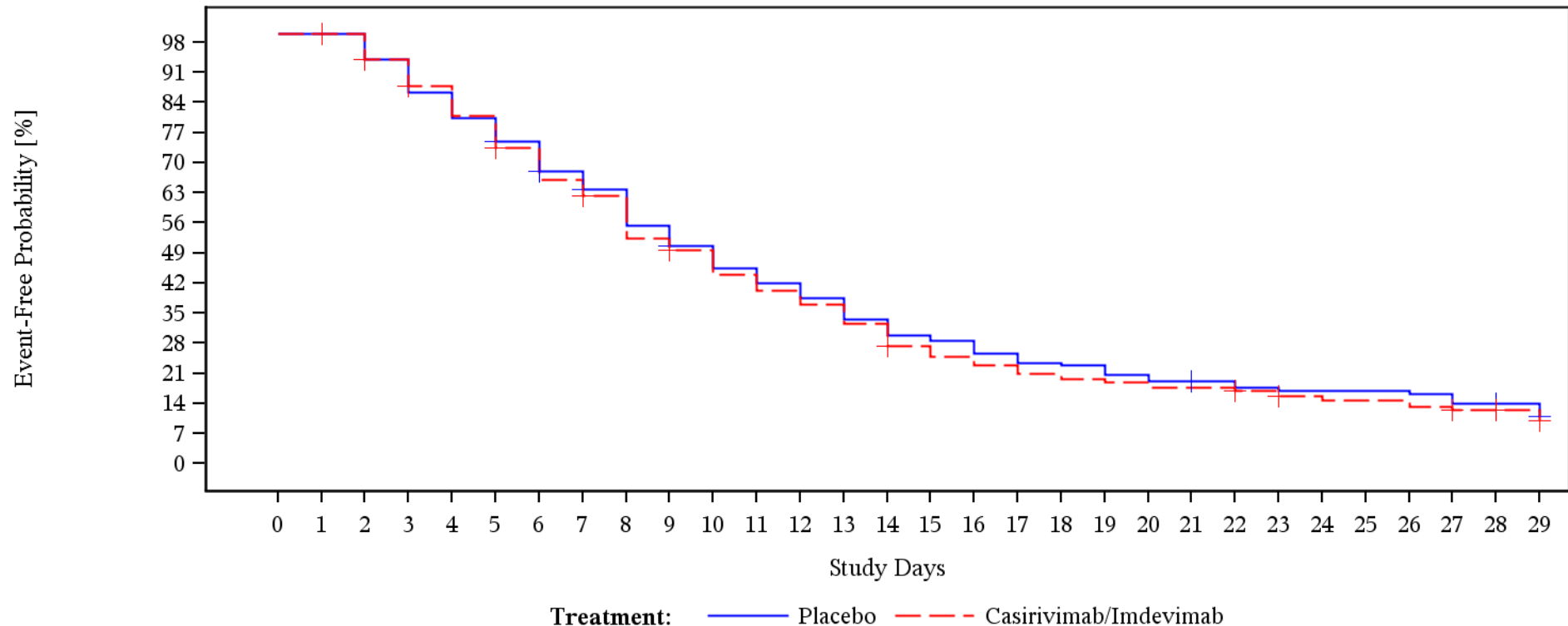
Placebo	813	813	503	471	456	435	410	388	363	324	286	256	230	203	190	167	153	130	114	105	98	88	82	77	71	68	64	58	53	34
Casirivimab/Imdevimab	798	798	499	466	434	405	380	349	321	265	224	193	171	151	134	116	101	91	85	76	66	59	56	51	47	39	37	34	32	19

Patients Censored

Placebo	0	310	312	313	313	314	316	319	319	321	321	321	322	323	323	323	323	324	325	325	327	327	328	328	329	330	331	335	350	379
Casirivimab/Imdevimab	0	299	301	301	301	301	303	304	305	305	305	305	305	306	307	307	307	307	309	309	311	311	312	313	316	317	318	318	329	344

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Positive



Patients At Risk

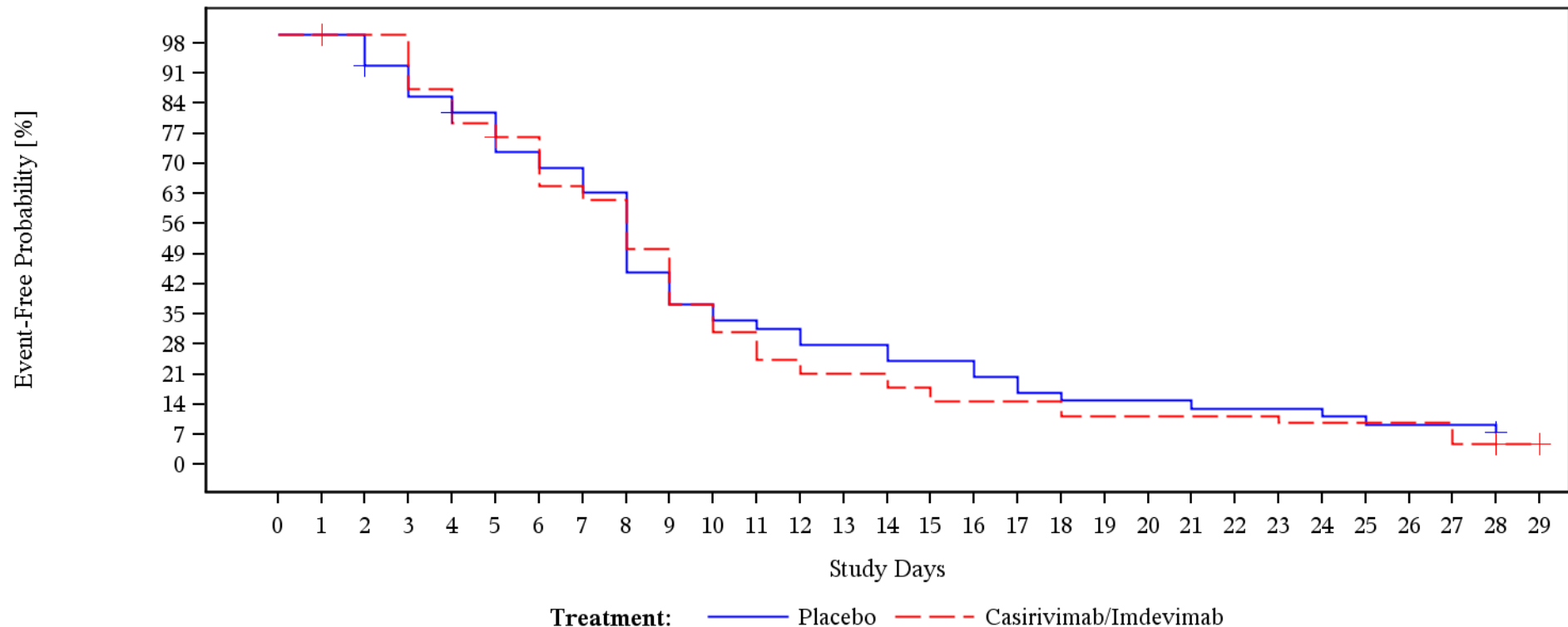
Placebo	284	284	149	138	127	118	109	98	91	79	71	64	59	54	47	42	40	36	33	32	29	27	26	24	23	23	23	22	19	14
Casirivimab/Imdevimab	311	311	165	153	142	131	118	106	99	83	78	69	63	58	51	42	38	35	32	30	29	27	27	24	20	19	19	17	15	10

Patients Censored

Placebo	0	135	137	137	137	138	139	140	140	141	141	141	141	141	141	141	141	141	141	141	141	142	142	142	142	142	142	142	147	158	
Casirivimab/Imdevimab	0	146	148	149	149	150	150	151	151	152	152	152	152	152	153	153	153	153	153	153	153	153	153	155	157	157	157	157	158	163	171

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified FAS Population
 ENDPOINT: Return to usual activities: Time to 'Yes'
 STUDYID: R10933-10987-COV-2067
 Baseline Serostatus=Other



Patients At Risk

Placebo	96	96	56	51	47	44	39	37	34	24	20	18	17	15	15	13	13	11	9	8	8	8	7	7	7	6	5	5	5	0
Casirivimab/Imdevimab	83	83	63	63	55	50	47	40	38	31	23	19	15	13	13	11	9	9	9	7	7	7	7	7	6	6	6	6	3	1

Patients Censored

Placebo	0	40	41	41	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	46	46	
Casirivimab/Imdevimab	0	20	20	20	20	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	23	24

Showing data observed through Day 29
 Clinical cutoff: 19AUG2021
 Program: f-km-plot.sas
 Output: f1-9-km-plot-subgrp-ttrtua.pdf

POPULATION: Modified Full Analysis Set

ENDPOINT: Return to usual activities: Time to 'Yes'

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					Interaction Test
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median		p-value	Hazard Ratio	95% Lower CL	95% Upper CL	
All	n/a	1192	100	652	54,698	540	45,302	6	5	6	9	8	9	1193	100	610	51,132	583	48,868	7	6	7	10	10	11	0,0003	1,213	1,086	1,354	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	579	48,574	321	55,44	258	44,56	6	5	6	9	8	9	580	48,617	300	51,724	280	48,276	7	6	8	11	10	12	0,0006	1,299	1,109	1,521	Convergence criterion (GCONV=1E-8) satisfied.	0,2618
	Female	613	51,426	331	53,997	282	46,003	6	5	6	9	8	10	613	51,383	310	50,571	303	49,429	6	5	7	10	9	11	0,0866	1,138	0,975	1,329	Convergence criterion (GCONV=1E-8) satisfied.	
Age	18-64	1043	87,5	584	55,992	459	44,008	6	5	6	9	8	9	1051	88,097	558	53,092	493	46,908	7	6	7	10	9	11	0,003	1,182	1,052	1,328	Convergence criterion (GCONV=1E-8) satisfied.	0,3388
	65-74	100	8,389	48	48	52	52	5	3	6	10	6	13	108	9,053	45	41,667	63	58,333	7	4	10	15	10	19	0,072	1,437	0,954	2,164	Convergence criterion (GCONV=1E-8) satisfied.	
	>=75	49	4,111	20	40,816	29	59,184	5	2	8	9	5	13	34	2,85	7	20,588	27	79,412	5	3	21	14	4	NE	0,1279	1,933	0,798	4,685	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline viral load categories	<=10^5 copies/mL	260	21,812	127	48,846	133	51,154	4	4	5	8	7	10	242	20,285	122	50,413	120	49,587	5	4	5	8	7	10	0,8338	0,975	0,76	1,25	Convergence criterion (GCONV=1E-8) satisfied.	0,1846
	>10^5 copies/mL - <=10^6 copies/mL	158	13,255	84	53,165	74	46,835	6	5	7	9	8	11	183	15,339	88	48,087	95	51,913	5	5	7	9	8	12	0,4153	1,127	0,834	1,521	Convergence criterion (GCONV=1E-8) satisfied.	
	>10^6 copies/mL - <=10^7 copies/mL	183	15,352	107	58,47	76	41,53	6	4	7	9	8	11	205	17,184	108	52,683	97	47,317	8	6	8	11	9	12	0,1355	1,214	0,929	1,587	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: Return to usual activities: Time to 'Yes'

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

		Casirivimab/Imdevimab											Placebo											Casirivimab/Imdevimab vs. Placebo								
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					log-rank		Hazard Ratio			Interaction Test			
Name	Level	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
	>10 ⁷ copies/mL	590	49,497	333	56,441	257	43,559	6	5	7	9	9	10	561	47,024	290	51,693	271	48,307	8	7	8	11	10	12	<.0001	1,366	1,166	1,6	Convergence criterion (GCONV=1E-8) satisfied.		
	Unknown	1	0,084	1	100	0	0	18	NE	NE	18	NE	NE	2	0,168	2	100	0	0	2	2	9	5,5	2	9	0,2253	0	0	NE	Convergence criterion (GCONV=1E-8) satisfied.		
Country	USA	1116	93,624	652	58,423	464	41,577	6	5	6	9	8	9	1112	93,21	610	54,856	502	45,144	7	6	7	10	10	11	0,0003	1,213	1,086	1,354	Convergence criterion (GCONV=1E-8) satisfied.		
	MEX	76	6,376	0	0	76	100	NE	NE	NE	NE	NE	NE	81	6,79	0	0	81	100	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	979	82,131	575	58,733	404	41,267	6	5	6	9	8	9	984	82,481	528	53,659	456	46,341	7	6	7	10	10	11	0,0003	1,228	1,091	1,382	Convergence criterion (GCONV=1E-8) satisfied.	0,7126	
	Black or African American	55	4,614	33	60	22	40	6	3	7	9	6	10	51	4,275	28	54,902	23	45,098	4	2	8	9	4	13	0,5422	1,161	0,695	1,939	Convergence criterion (GCONV=1E-8) satisfied.		
	Asian/American Indian Alaska Native/Native Hawaiian or other Pacific Islander	85	7,131	26	30,588	59	69,412	8	3	9	10	9	14	70	5,868	27	38,571	43	61,429	6	2	11	12	8	14	0,8963	0,966	0,562	1,661	Convergence criterion (GCONV=1E-8) satisfied.		
	Unknown/Not Reported	73	6,124	18	24,658	55	75,342	5	2	7	8	5	11	88	7,376	27	30,682	61	69,318	7	5	10	12	8	15	0,8012	1,078	0,59	1,968	Convergence criterion (GCONV=1E-8) satisfied.		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

POPULATION: Modified Full Analysis Set

ENDPOINT: Return to usual activities: Time to 'Yes'

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Time to Event analysis (efficacy)

Name	Level	Casirivimab/Imdevimab												Placebo												Casirivimab/Imdevimab vs. Placebo					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
		n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (days)	95% Lower CL for Q1	95% Upper CL for Q1	Median (days)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Baseline serostatus	Negative	798	66,946	453	56,767	345	43,233	6	5	6	9	8	9	813	68,148	434	53,383	379	46,617	7	6	8	11	10	12	0,0001	1,283	1,124	1,464	Convergence criterion (GCONV=1E-8) satisfied.	0,1819
	Positive	311	26,091	140	45,016	171	54,984	5	4	6	9	8	11	284	23,806	126	44,366	158	55,634	5	4	6	10	8	11	0,6738	1,051	0,826	1,337	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	83	6,963	59	71,084	24	28,916	6	4	7	9	7	9	96	8,047	50	52,083	46	47,917	5	3	7	8	7	9	0,6946	1,073	0,736	1,566	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.

* indicates convergence problem. Result is uninterpretable

Clinical cut-off: 19Aug2021.

Datenschnitt 19.08.2021 (DCO2)

Wirksamkeit

Ergänzende Dokumente

**Table 1.3: Number of patients for each subgroup and category per arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 1193)	Casirivimab/Imdevimab (N = 1192)
Sex [n (%)]		
Male	580 (48.6)	579 (48.6)
Female	613 (51.4)	613 (51.4)
Age [n (%)]		
18-64	1051 (88.1)	1043 (87.5)
65-74	108 (9.1)	100 (8.4)
>=75	34 (2.8)	49 (4.1)
Baseline viral load categories [n (%)]		
<=10 ⁵ copies/mL	242 (20.3)	260 (21.8)
>10 ⁵ copies/mL - <=10 ⁶ copies/mL	183 (15.3)	158 (13.3)
>10 ⁶ copies/mL - <=10 ⁷ copies/mL	205 (17.2)	183 (15.4)
>10 ⁷ copies/mL	561 (47.0)	590 (49.5)
Unknown	2 (0.2)	1 (0.1)
Country [n (%)]		
United States	1112 (93.2)	1116 (93.6)
Mexico	81 (6.8)	76 (6.4)
Race/ethnicity [n (%)]		
White	984 (82.5)	979 (82.1)
Black or African American	51 (4.3)	55 (4.6)
Asian/American Indian Alaska Native/Native Hawaiian or other Pacific Islander	70 (5.9)	85 (7.1)
Unknown/Not Reported	88 (7.4)	73 (6.1)
Baseline SARS-CoV-2 Serology Status [n (%)]		
Negative	813 (68.1)	798 (66.9)
Positive	284 (23.8)	311 (26.1)
Other	96 (8.0)	83 (7.0)

POPULATION: mFAS
 ENDPOINT: --
 MODEL: --
 STUDY: R10933-10987-COV-2067
 Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm (mFAS Population)

Category	Center				Country				Geographical region ³			
	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷	n ⁴	% ⁵	n of patients randomized ⁶	% randomized patients ⁷
Overall	76	100%	2385	100%	2	100%	2385	100%	2	100%	2385	100%
with <10 Patients per arm ¹	49	64.5%	409	17.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
with >=10 Patients per arm ²	27	35.5%	1976	82.9%	2	100%	2385	100%	2	100%	2385	100%

¹: '<10 patients category' if at least one treatment arm has <10 patients

²: '>=10 patients' category if all treatment arms have >=10 patients

³: Geographical regions: United States; Rest of the World

⁴: Number of centers, countries, or geographical regions

⁵: % of centers compared to overall number of centers, % of countries compared to overall number of countries, % of geographical regions compared to overall number of geographical regions

⁶: Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)

⁷: % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)

Clinical cut-off: 19Aug2021

Program: t3-center.sas

Output: t3-center.sas

**Table 4: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 1193)	Casirivimab/Imdevimab (N = 1192)
Age (Years)		
n	1193	1192
Mean	47.23	47.96
SD	14.55	14.69
Median	48.0	49.0
Q1	36.0	37.0
Q3	57.000	57.500
Min	18.0	18.0
Max	90.0	91.0
Age Group (Years) [n (%)]		
18 - 44	486 (40.7)	472 (39.6)
45 - 64	565 (47.4)	571 (47.9)
65 - 84	137 (11.5)	141 (11.8)
>=85	5 (0.4)	8 (0.7)
Age Group 2 (Years) [n (%)]		
>=50	565 (47.4)	594 (49.8)
<50	628 (52.6)	598 (50.2)
Age Group 3 (Years) [n (%)]		
>=65	142 (11.9)	149 (12.5)
<65	1051 (88.1)	1043 (87.5)
Age Group 4 (Years) [n (%)]		
>=75	34 (2.8)	49 (4.1)
<75	1159 (97.2)	1143 (95.9)
Sex [n (%)]		
Male	580 (48.6)	579 (48.6)
Female	613 (51.4)	613 (51.4)
Ethnicity [n (%)]		
Hispanic or Latino	567 (47.5)	575 (48.2)
Not Hispanic or Latino	617 (51.7)	604 (50.7)
Not Reported	9 (0.8)	13 (1.1)

**Table 4: Demographic and Baseline Characteristics per arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 1193)	Casirivimab/Imdevimab (N = 1192)
Race [n (%)]		
White	984 (82.5)	979 (82.1)
Black or African American	51 (4.3)	55 (4.6)
Asian	47 (3.9)	48 (4.0)
American Indian or Alaska Native	21 (1.8)	34 (2.9)
Native Hawaiian or Other Pacific Islander	2 (0.2)	3 (0.3)
Unknown	61 (5.1)	52 (4.4)
Not Reported	27 (2.3)	21 (1.8)
Weight (kg)		
n	1193	1191
Missing	0	1
Mean	89.76	90.61
SD	22.64	23.00
Median	87.5	86.7
Q1	74.0	75.0
Q3	103.000	102.100
Min	43.1	36.7
Max	208.7	228.6
Height (cm)		
n	1193	1191
Missing	0	1
Mean	168.58	168.84
SD	11.17	10.76
Median	167.6	169.0
Q1	160.0	161.3
Q3	177.000	176.000
Min	120.0	123.0
Max	210.8	200.7
BMI (kg/m2)		
n	1193	1191
Missing	0	1
Mean	31.42	31.71
SD	6.66	7.17
Median	30.9	30.7
Q1	26.6	27.0
Q3	34.700	34.700
Min	17.9	17.2
Max	65.9	67.3
Obesity [n (%)]		
Missing	0 (0.0)	1 (0.1)
BMI < 30 kg/m2	488 (40.9)	504 (42.3)
BMI >= 30 kg/m2	705 (59.1)	687 (57.6)

Table 4: Demographic and Baseline Characteristics per arm Modified Full Analysis Set

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 1193)	Casirivimab/Imdevimab (N = 1192)
Baseline Viral Load in NP Swab (copies/mL)		
n	1191	1191
Missing	2	1
Mean	3.5201E8	4.1274E8
SD	1.1547E9	1.4745E9
Median	7260000	8890000
Q1	229000.0	181000.0
Q3	1.55E8	2.15E8
Min	357.0	357.0
Max	1.61E10	2.97E10
SARS-CoV-2 results from central lab - NP Swab (log10 copies/mL)		
n	1191	1191
Missing	2	1
Mean	6.65	6.72
SD	1.82	1.87
Median	6.9	6.9
Q1	5.4	5.3
Q3	8.190	8.332
Min	2.6	2.6
Max	10.2	10.5
Baseline Qualitative RT-PCR results [n (%)]		
Missing	2 (0.2)	1 (0.1)
Positive (>=LLOD)	1191 (99.8)	1191 (99.9)
Baseline Serology Status [n (%)]		
Negative	813 (68.1)	798 (66.9)
Positive	284 (23.8)	311 (26.1)
Other	96 (8.0)	83 (7.0)
C-Reactive Protein (mg/L)		
n	1173	1172
Missing	20	20
Mean	13.36	13.35
SD	25.20	25.10
Median	5.1	5.2
Q1	2.1	2.0
Q3	11.710	12.660
Min	0.2	0.1
Max	256.6	323.3
Time from symptom onset to randomization (days)		
n	1193	1192
Mean	3.25	3.30
SD	1.73	1.79
Median	3.0	3.0
Q1	2.0	2.0
Q3	5.000	5.000
Min	0.0	0.0
Max	7.0	7.0

Table 5.1. Summary of Overall Patient Disposition
Phase 3 Cohort 1 with ≥ 1 Risk Factor for Severe COVID-19 post PA6
Modified Full Analysis Set

	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Randomized patients	1193 (100%)	1192 (100%)
Randomized patients but not treated	0	1 (<0.1%)
Patients who completed the study	1128 (94.6%)	1137 (95.4%)
Patients ongoing in the study	2 (0.2%)	0
Patients who discontinued the study	63 (5.3%)	55 (4.6%)
Reasons for study discontinuation		
Adverse Event	2 (0.2%)	1 (<0.1%)
Pregnancy	0	0
Lack of Efficacy	0	0
Physician Decision	0	0
Sponsor Request	0	0
Death	7 (0.6%)	1 (<0.1%)
Lost To Follow-Up	30 (2.5%)	28 (2.3%)
Subject Decision	24 (2.0%)	25 (2.1%)

Clinical cut-off: 19Aug2021

Table 5.2. Number of screened patients and reason for screening failure
All Screened Subjects

	Total (N=8277)
Number of Subjects Screened	8277
Randomized Subject	7939 (95.9%)
Subjects treated but not randomized	0
Subjects randomized but not treated	111 (1.3%)
Screen phase discontinuation	338 (4.1%)
Primary reasons for screen phase discontinuation	
Adverse Event	1 (<0.1%)
Other	29 (0.4%)
Screen Failure	287 (3.5%)
Subject Decision	21 (0.3%)

Clinical cut-off: 19Aug2021

**Table 2.2: Duration of Follow-up by domain and arm
Modified Full Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 1193)	Casirivimab/Imdevimab (N = 1192)
Efficacy Follow-up (Days)		
Median	29.0	29.0
Safety 1 Follow-up (Days)		
Missing	0	1
Median	29.0	29.0
Safety 2 Follow-up (Days)		
Missing	0	1
Median	169.0	169.0

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant medication	786 (65.9%)	789 (66.2%)
ANALGESICS	290 (24.3%)	300 (25.2%)
ANILIDES	264 (22.1%)	264 (22.1%)
PARACETAMOL	245 (20.5%)	251 (21.1%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	11 (0.9%)	4 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE HYDROCHLORIDE	8 (0.7%)	5 (0.4%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	4 (0.3%)	3 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYL EPHRINE HYDROCHLORIDE	1 (0.1%)	3 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	2 (0.2%)	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	2 (0.2%)	0
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRIN E	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL;SALICYLAMIDE	0	1 (0.1%)
BUTALBITAL;CAFFEINE;PARACETAMOL	1 (0.1%)	0
CAFFEINE;PARACETAMOL	1 (0.1%)	0
CHLORPHENAMINE MALEATE;PARACETAMOL	0	1 (0.1%)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE	0	1 (0.1%)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	1 (0.1%)	0
DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0
IBUPROFEN;PARACETAMOL	0	1 (0.1%)
PARACETAMOL;PHENYLEPHRINE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
OTHER ANALGESICS AND ANTIPYRETICS	16 (1.3%)	19 (1.6%)
GABAPENTIN	12 (1.0%)	14 (1.2%)
PREGABALIN	2 (0.2%)	2 (0.2%)
DULOXETINE	1 (0.1%)	2 (0.2%)
AMITRIPTYLINE	0	1 (0.1%)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.1%)	0
OTHER ANTIMIGRAINE PREPARATIONS	2 (0.2%)	13 (1.1%)
METOPROLOL	0	4 (0.3%)
TOPIRAMATE	0	4 (0.3%)
AMITRIPTYLINE	1 (0.1%)	2 (0.2%)
BOTULINUM TOXIN TYPE A	0	2 (0.2%)
VENLAFAXINE	1 (0.1%)	0
VERAPAMIL	0	1 (0.1%)
SELECTIVE SEROTONIN (5HT1) AGONISTS	8 (0.7%)	4 (0.3%)
SUMATRIPTAN	4 (0.3%)	4 (0.3%)
RIZATRIPTAN	2 (0.2%)	0
SUMATRIPTAN SUCCINATE	2 (0.2%)	0
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	3 (0.3%)	7 (0.6%)
HYDROCODONE BITARTRATE;PARACETAMOL	2 (0.2%)	2 (0.2%)
CODEINE;PARACETAMOL	0	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
HYDROCODONE;PARACETAMOL	1 (0.1%)	1 (0.1%)
CODEINE PHOSPHATE;PARACETAMOL	0	1 (0.1%)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	0	1 (0.1%)
SALICYLIC ACID AND DERIVATIVES	5 (0.4%)	4 (0.3%)
ACETYLSALICYLIC ACID	5 (0.4%)	3 (0.3%)
ACETYLSALICYLIC ACID;CAFFEINE	0	1 (0.1%)
OTHER OPIOIDS	2 (0.2%)	6 (0.5%)
TRAMADOL	2 (0.2%)	6 (0.5%)
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS	0	3 (0.3%)
ERENUMAB	0	1 (0.1%)
FREMANEZUMAB	0	1 (0.1%)
GALCANEZUMAB	0	1 (0.1%)
NATURAL OPIUM ALKALOIDS	1 (0.1%)	2 (0.2%)
OXYCODONE	1 (0.1%)	1 (0.1%)
MORPHINE	0	1 (0.1%)
PYRAZOLONES	0	1 (0.1%)
METAMIZOLE	0	1 (0.1%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	233 (19.5%)	248 (20.8%)
ACE INHIBITORS, PLAIN	119 (10.0%)	133 (11.2%)
LISINOPRIL	99 (8.3%)	100 (8.4%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ENALAPRIL	12 (1.0%)	16 (1.3%)
BENAZEPRIL	2 (0.2%)	7 (0.6%)
CAPTOPRIL	0	7 (0.6%)
RAMIPRIL	3 (0.3%)	4 (0.3%)
BENAZEPRIL HYDROCHLORIDE	1 (0.1%)	0
ENALAPRIL MALEATE	1 (0.1%)	0
FOSINOPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	105 (8.8%)	101 (8.5%)
LOSARTAN	81 (6.8%)	61 (5.1%)
VALSARTAN	8 (0.7%)	11 (0.9%)
OLMESARTAN	5 (0.4%)	6 (0.5%)
TELMISARTAN	4 (0.3%)	6 (0.5%)
OLMESARTAN MEDOXOMIL	3 (0.3%)	6 (0.5%)
IRBESARTAN	2 (0.2%)	4 (0.3%)
LOSARTAN POTASSIUM	3 (0.3%)	3 (0.3%)
CANDESARTAN	0	3 (0.3%)
AZILSARTAN KAMEDOXOMIL	0	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	2 (0.2%)	6 (0.5%)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	2 (0.2%)	1 (0.1%)
HYDROCHLOROTHIAZIDE;LOSARTAN	0	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
HYDROCHLOROTHIAZIDE;IRBESARTAN	0	1 (0.1%)
HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	1 (0.1%)
HYDROCHLOROTHIAZIDE;VALSARTAN	0	1 (0.1%)
ACE INHIBITORS AND DIURETICS	2 (0.2%)	5 (0.4%)
HYDROCHLOROTHIAZIDE;LISINOPRIL	2 (0.2%)	5 (0.4%)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	3 (0.3%)	1 (0.1%)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	2 (0.2%)	1 (0.1%)
AMLODIPINE;BENAZEPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS	2 (0.2%)	1 (0.1%)
SACUBITRIL VALSARTAN SODIUM HYDRATE	2 (0.2%)	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	0	1 (0.1%)
AMLODIPINE BESILATE;VALSARTAN	0	1 (0.1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	152 (12.7%)	130 (10.9%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	117 (9.8%)	99 (8.3%)
SALBUTAMOL	99 (8.3%)	83 (7.0%)
SALBUTAMOL SULFATE	15 (1.3%)	11 (0.9%)
LEVOSALBUTAMOL	1 (0.1%)	2 (0.2%)
PROCATEROL HYDROCHLORIDE	2 (0.2%)	1 (0.1%)
FORMOTEROL	1 (0.1%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
LEVOSALBUTAMOL HYDROCHLORIDE	1 (0.1%)	0
LEVOSALBUTAMOL TARTRATE	0	1 (0.1%)
SALMETEROL	0	1 (0.1%)
TERBUTALINE	0	1 (0.1%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	26 (2.2%)	20 (1.7%)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	10 (0.8%)	8 (0.7%)
BUDESONIDE;FORMOTEROL FUMARATE	8 (0.7%)	7 (0.6%)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	7 (0.6%)	3 (0.3%)
FLUTICASONE FUROATE;VILANTEROL	1 (0.1%)	0
FLUTICASONE PROPIONATE;SALMETEROL	0	1 (0.1%)
FORMOTEROL FUMARATE;MOMETASONE FUROATE	0	1 (0.1%)
LEUKOTRIENE RECEPTOR ANTAGONISTS	19 (1.6%)	24 (2.0%)
MONTELUKAST	12 (1.0%)	14 (1.2%)
MONTELUKAST SODIUM	7 (0.6%)	10 (0.8%)
GLUCOCORTICOIDS	14 (1.2%)	15 (1.3%)
FLUTICASONE PROPIONATE	4 (0.3%)	5 (0.4%)
BECLOMETASONE DIPROPIONATE	2 (0.2%)	4 (0.3%)
BUDESONIDE	3 (0.3%)	3 (0.3%)
FLUTICASONE	5 (0.4%)	0
BECLOMETASONE	0	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CICLESONIDE	0	1 (0.1%)
MOMETASONE FUROATE	1 (0.1%)	0
ANTICHOLINERGICS	8 (0.7%)	7 (0.6%)
IPRATROPIUM	2 (0.2%)	3 (0.3%)
IPRATROPIUM BROMIDE	4 (0.3%)	1 (0.1%)
TIOTROPIUM BROMIDE MONOHYDRATE	1 (0.1%)	2 (0.2%)
GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
UMECLIDINIUM BROMIDE	1 (0.1%)	0
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	7 (0.6%)	5 (0.4%)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	2 (0.2%)	2 (0.2%)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	3 (0.3%)	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
IPRATROPIUM BROMIDE;SALBUTAMOL	0	1 (0.1%)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	1 (0.1%)	0
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	1 (0.1%)	0
UMECLIDINIUM;VILANTEROL	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0	1 (0.1%)
OMALIZUMAB	0	1 (0.1%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	139 (11.7%)	130 (10.9%)
PROPIONIC ACID DERIVATIVES	122 (10.2%)	109 (9.1%)
IBUPROFEN	107 (9.0%)	92 (7.7%)
NAPROXEN	8 (0.7%)	11 (0.9%)
NAPROXEN SODIUM	8 (0.7%)	5 (0.4%)
HYDROCODONE BITARTRATE;IBUPROFEN	0	1 (0.1%)
OXICAMS	10 (0.8%)	7 (0.6%)
MELOXICAM	10 (0.8%)	7 (0.6%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	6 (0.5%)	7 (0.6%)
DICLOFENAC	2 (0.2%)	2 (0.2%)
DICLOFENAC POTASSIUM	2 (0.2%)	1 (0.1%)
DICLOFENAC SODIUM	1 (0.1%)	1 (0.1%)
ETODOLAC	0	2 (0.2%)
INDOMETACIN	1 (0.1%)	0
KETOROLAC	0	1 (0.1%)
KETOROLAC TROMETHAMINE	1 (0.1%)	0
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	3 (0.3%)	7 (0.6%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
BENZYDAMINE	1 (0.1%)	1 (0.1%)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	0	2 (0.2%)
BENZYDAMINE HYDROCHLORIDE	0	1 (0.1%)
COLLAGEN	1 (0.1%)	0
GLUCOSAMINE	0	1 (0.1%)
GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	0	1 (0.1%)
GLUCOSAMINE SULFATE	1 (0.1%)	0
SULFASALAZINE	0	1 (0.1%)
COXIBS	2 (0.2%)	1 (0.1%)
CELECOXIB	2 (0.2%)	1 (0.1%)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	0	2 (0.2%)
CURCUMA LONGA	0	2 (0.2%)
OTHER ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH OTHER DRUGS	1 (0.1%)	0
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
LIPID MODIFYING AGENTS	100 (8.4%)	136 (11.4%)
HMG COA REDUCTASE INHIBITORS	92 (7.7%)	121 (10.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ATORVASTATIN	31 (2.6%)	56 (4.7%)
SIMVASTATIN	19 (1.6%)	21 (1.8%)
ROSUVASTATIN	13 (1.1%)	19 (1.6%)
ROSUVASTATIN CALCIUM	7 (0.6%)	14 (1.2%)
ATORVASTATIN CALCIUM	9 (0.8%)	5 (0.4%)
PRAVASTATIN	6 (0.5%)	5 (0.4%)
LOVASTATIN	4 (0.3%)	2 (0.2%)
PRAVASTATIN SODIUM	1 (0.1%)	2 (0.2%)
PITAVASTATIN CALCIUM	2 (0.2%)	0
OTHER LIPID MODIFYING AGENTS	9 (0.8%)	22 (1.8%)
FISH OIL	6 (0.5%)	6 (0.5%)
EZETIMIBE	2 (0.2%)	6 (0.5%)
OMEGA-3 NOS	1 (0.1%)	4 (0.3%)
EICOSAPENTAENOIC ACID ETHYL ESTER	0	4 (0.3%)
ALIROCUMAB	1 (0.1%)	0
EVOLOCUMAB	0	1 (0.1%)
OMEGA-3-ACID ETHYL ESTER	0	1 (0.1%)
SITOSTEROL	0	1 (0.1%)
FIBRATES	4 (0.3%)	7 (0.6%)
FENOFIBRATE	4 (0.3%)	4 (0.3%)
GEMFIBROZIL	0	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CHOLINE FENOFIBRATE	0	1 (0.1%)
COMBINATIONS OF VARIOUS LIPID MODIFYING AGENTS	2 (0.2%)	0
EZETIMIBE;SIMVASTATIN	2 (0.2%)	0
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	1 (0.1%)	1 (0.1%)
CARTHAMUS TINCTORIUS OIL	1 (0.1%)	0
MONASCUS PURPUREUS	0	1 (0.1%)
NICOTINIC ACID AND DERIVATIVES	0	1 (0.1%)
NICOTINIC ACID	0	1 (0.1%)
ANTITHROMBOTIC AGENTS	110 (9.2%)	100 (8.4%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	84 (7.0%)	89 (7.5%)
ACETYLSALICYLIC ACID	83 (7.0%)	82 (6.9%)
CLOPIDOGREL	3 (0.3%)	8 (0.7%)
CLOPIDOGREL BISULFATE	1 (0.1%)	4 (0.3%)
PRASUGREL	0	2 (0.2%)
EPOPROSTENOL	1 (0.1%)	0
PRASUGREL HYDROCHLORIDE	0	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	19 (1.6%)	10 (0.8%)
APIXABAN	14 (1.2%)	7 (0.6%)
RIVAROXABAN	5 (0.4%)	3 (0.3%)
HEPARIN GROUP	16 (1.3%)	3 (0.3%)
ENOXAPARIN	9 (0.8%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ENOXAPARIN SODIUM	7 (0.6%)	2 (0.2%)
HEPARIN SODIUM	1 (0.1%)	0
VITAMIN K ANTAGONISTS	0	1 (0.1%)
WARFARIN	0	1 (0.1%)
ANTIBACTERIALS FOR SYSTEMIC USE	94 (7.9%)	92 (7.7%)
MACROLIDES	57 (4.8%)	63 (5.3%)
AZITHROMYCIN	54 (4.5%)	61 (5.1%)
CLARITHROMYCIN	1 (0.1%)	2 (0.2%)
AZITHROMYCIN DIHYDRATE	1 (0.1%)	0
ERYTHROMYCIN	1 (0.1%)	0
THIRD-GENERATION CEPHALOSPORINS	18 (1.5%)	14 (1.2%)
CEFTRIAZONE	10 (0.8%)	4 (0.3%)
CEFDINIR	5 (0.4%)	5 (0.4%)
CEFTRIAZONE SODIUM	4 (0.3%)	4 (0.3%)
CEFPODOXIME PROXETIL	0	1 (0.1%)
TETRACYCLINES	11 (0.9%)	5 (0.4%)
DOXYCYCLINE	10 (0.8%)	5 (0.4%)
MINOCYCLINE	1 (0.1%)	0
FLUOROQUINOLONES	6 (0.5%)	8 (0.7%)
LEVOFLOXACIN	3 (0.3%)	7 (0.6%)
CIPROFLOXACIN	3 (0.3%)	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PENICILLINS WITH EXTENDED SPECTRUM	4 (0.3%)	6 (0.5%)
AMOXICILLIN	4 (0.3%)	4 (0.3%)
AMPICILLIN	0	2 (0.2%)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	5 (0.4%)	3 (0.3%)
AMOXICILLIN;CLAVULANIC ACID	4 (0.3%)	3 (0.3%)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	1 (0.1%)	0
ANTIBACTERIALS FOR SYSTEMIC USE	1 (0.1%)	2 (0.2%)
PENICILLIN NOS	0	2 (0.2%)
BROAD SPECTRUM ANTIBIOTICS	1 (0.1%)	0
FIRST-GENERATION CEPHALOSPORINS	1 (0.1%)	2 (0.2%)
CEFALEXIN	1 (0.1%)	2 (0.2%)
NITROFURAN DERIVATIVES	0	3 (0.3%)
NITROFURANTOIN	0	3 (0.3%)
GLYCOPEPTIDE ANTIBACTERIALS	1 (0.1%)	1 (0.1%)
VANCOMYCIN	1 (0.1%)	1 (0.1%)
INTERMEDIATE-ACTING SULFONAMIDES	1 (0.1%)	1 (0.1%)
SULFAMETHOXAZOLE	1 (0.1%)	1 (0.1%)
TRIMETHOPRIM AND DERIVATIVES	1 (0.1%)	1 (0.1%)
TRIMETHOPRIM	1 (0.1%)	1 (0.1%)
CARBAPENEMS	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
MEROPENEM	1 (0.1%)	0
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	0	1 (0.1%)
SULFAMETHOXAZOLE;TRIMETHOPRIM	0	1 (0.1%)
FOURTH-GENERATION CEPHALOSPORINS	0	1 (0.1%)
CEFEPIME	0	1 (0.1%)
IMIDAZOLE DERIVATIVES	0	1 (0.1%)
METRONIDAZOLE	0	1 (0.1%)
LINCOSAMIDES	0	1 (0.1%)
LINCOMYCIN	0	1 (0.1%)
OTHER ANTIBACTERIALS	1 (0.1%)	0
METHENAMINE	1 (0.1%)	0
VITAMINS	95 (8.0%)	90 (7.6%)
VITAMIN D AND ANALOGUES	57 (4.8%)	52 (4.4%)
VITAMIN D NOS	36 (3.0%)	34 (2.9%)
COLECALCIFEROL	20 (1.7%)	18 (1.5%)
ERGOCALCIFEROL	2 (0.2%)	0
ASCORBIC ACID (VITAMIN C), PLAIN	48 (4.0%)	50 (4.2%)
ASCORBIC ACID	48 (4.0%)	50 (4.2%)
MULTIVITAMINS, PLAIN	19 (1.6%)	25 (2.1%)
VITAMINS NOS	18 (1.5%)	25 (2.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ASCORBIC ACID;CALCIUM PANTOTHENATE;COLECALCIFEROL;CYANOCOBALAMIN ;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1 (0.1%)	0
OTHER PLAIN VITAMIN PREPARATIONS	5 (0.4%)	4 (0.3%)
BIOTIN	2 (0.2%)	1 (0.1%)
VITAMIN B NOS	2 (0.2%)	1 (0.1%)
NICOTINAMIDE	1 (0.1%)	0
TOCOPHERYL ACETATE	0	1 (0.1%)
VITAMIN E NOS	0	1 (0.1%)
MULTIVITAMINS WITH MINERALS	3 (0.3%)	4 (0.3%)
MINERALS NOS;VITAMINS NOS	3 (0.3%)	3 (0.3%)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID;	0	1 (0.1%)
COMBINATIONS OF VITAMINS	4 (0.3%)	0
ASCORBIC ACID;VITAMIN D NOS	1 (0.1%)	0
COLECALCIFEROL;MENAQUINONE-7	1 (0.1%)	0
COLECALCIFEROL;RETINOL;TOCOPHEROL	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
VITAMINS NOS	1 (0.1%)	0
VITAMIN B-COMPLEX, PLAIN	3 (0.3%)	0
VITAMIN B NOS	2 (0.2%)	0
VITAMIN B COMPLEX	1 (0.1%)	0
VITAMIN B1, PLAIN	1 (0.1%)	2 (0.2%)
SULBUTIAMINE	0	1 (0.1%)
THIAMINE	0	1 (0.1%)
THIAMINE HYDROCHLORIDE	1 (0.1%)	0
VITAMINS, OTHER COMBINATIONS	2 (0.2%)	1 (0.1%)
ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM;MANGANES E;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	2 (0.2%)	1 (0.1%)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.1%)	1 (0.1%)
MINERALS NOS;VITAMINS NOS	1 (0.1%)	1 (0.1%)
VITAMIN A, PLAIN	1 (0.1%)	1 (0.1%)
VITAMIN A NOS	1 (0.1%)	1 (0.1%)
VITAMINS WITH MINERALS	2 (0.2%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID;	2 (0.2%)	0
VITAMIN A AND D IN COMBINATION	1 (0.1%)	0
COD-LIVER OIL	1 (0.1%)	0
DRUGS USED IN DIABETES	91 (7.6%)	87 (7.3%)
BIGUANIDES	69 (5.8%)	66 (5.5%)
METFORMIN	65 (5.4%)	66 (5.5%)
METFORMIN HYDROCHLORIDE	4 (0.3%)	0
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	18 (1.5%)	8 (0.7%)
INSULIN LISPRO	10 (0.8%)	4 (0.3%)
INSULIN ASPART	6 (0.5%)	2 (0.2%)
INSULIN	1 (0.1%)	2 (0.2%)
INSULIN HUMAN	1 (0.1%)	0
SULFONYLUREAS	11 (0.9%)	14 (1.2%)
GLIPIZIDE	8 (0.7%)	9 (0.8%)
GLIBENCLAMIDE	1 (0.1%)	3 (0.3%)
GLIMEPIRIDE	2 (0.2%)	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	12 (1.0%)	10 (0.8%)
INSULIN GLARGINE	7 (0.6%)	9 (0.8%)
INSULIN DETEMIR	4 (0.3%)	0
INSULIN DEGLUDEC	2 (0.2%)	1 (0.1%)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	6 (0.5%)	9 (0.8%)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	2 (0.2%)	5 (0.4%)
EMPAGLIFLOZIN	4 (0.3%)	2 (0.2%)
CANAGLIFLOZIN	0	2 (0.2%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	7 (0.6%)	7 (0.6%)
SITAGLIPTIN PHOSPHATE	6 (0.5%)	5 (0.4%)
GEMIGLIPTIN	0	1 (0.1%)
LINAGLIPTIN	1 (0.1%)	0
SITAGLIPTIN	0	1 (0.1%)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES	9 (0.8%)	3 (0.3%)
DULAGLUTIDE	4 (0.3%)	1 (0.1%)
SEMAGLUTIDE	3 (0.3%)	2 (0.2%)
EXENATIDE	1 (0.1%)	0
LIRAGLUTIDE	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	2 (0.2%)	4 (0.3%)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	2 (0.2%)	1 (0.1%)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	0	2 (0.2%)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	0	1 (0.1%)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	3 (0.3%)	1 (0.1%)
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	2 (0.2%)	1 (0.1%)
INSULIN HUMAN INJECTION, ISOPHANE	1 (0.1%)	0
THIAZOLIDINEDIONES	1 (0.1%)	2 (0.2%)
PIOGLITAZONE	0	2 (0.2%)
PIOGLITAZONE HYDROCHLORIDE	1 (0.1%)	0
ALPHA GLUCOSIDASE INHIBITORS	1 (0.1%)	0
ACARBOSE	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	0	1 (0.1%)
INSULIN ASPART;INSULIN ASPART PROTAMINE	0	1 (0.1%)
BETA BLOCKING AGENTS	69 (5.8%)	69 (5.8%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
BETA BLOCKING AGENTS, SELECTIVE	51 (4.3%)	57 (4.8%)
METOPROLOL	29 (2.4%)	28 (2.3%)
ATENOLOL	16 (1.3%)	15 (1.3%)
NEBIVOLOL HYDROCHLORIDE	1 (0.1%)	6 (0.5%)
METOPROLOL TARTRATE	3 (0.3%)	3 (0.3%)
METOPROLOL SUCCINATE	1 (0.1%)	4 (0.3%)
BISOPROLOL	1 (0.1%)	1 (0.1%)
ALPHA AND BETA BLOCKING AGENTS	15 (1.3%)	9 (0.8%)
CARVEDILOL	13 (1.1%)	9 (0.8%)
LABETALOL	2 (0.2%)	0
LABETALOL HYDROCHLORIDE	1 (0.1%)	0
BETA BLOCKING AGENTS, NON-SELECTIVE	2 (0.2%)	4 (0.3%)
PROPRANOLOL	2 (0.2%)	2 (0.2%)
SOTALOL	0	2 (0.2%)
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	1 (0.1%)	0
BISOPROLOL;HYDROCHLOROTHIAZIDE	1 (0.1%)	0
CALCIUM CHANNEL BLOCKERS	59 (4.9%)	74 (6.2%)
DIHYDROPYRIDINE DERIVATIVES	53 (4.4%)	70 (5.9%)
AMLODIPINE	43 (3.6%)	60 (5.0%)
NIFEDIPINE	5 (0.4%)	5 (0.4%)
AMLODIPINE BESILATE	5 (0.4%)	4 (0.3%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
FELODIPINE	0	1 (0.1%)
BENZOTHIAZEPINE DERIVATIVES	4 (0.3%)	3 (0.3%)
DILTIAZEM	4 (0.3%)	2 (0.2%)
DILTIAZEM HYDROCHLORIDE	0	1 (0.1%)
PHENYLALKYLAMINE DERIVATIVES	2 (0.2%)	1 (0.1%)
VERAPAMIL	2 (0.2%)	1 (0.1%)
DIURETICS	69 (5.8%)	64 (5.4%)
THIAZIDES, PLAIN	48 (4.0%)	46 (3.9%)
HYDROCHLOROTHIAZIDE	48 (4.0%)	46 (3.9%)
SULFONAMIDES, PLAIN	13 (1.1%)	13 (1.1%)
FUROSEMIDE	5 (0.4%)	10 (0.8%)
CHLORTALIDONE	5 (0.4%)	2 (0.2%)
BUMETANIDE	1 (0.1%)	1 (0.1%)
INDAPAMIDE	2 (0.2%)	0
TORASEMIDE	1 (0.1%)	0
ALDOSTERONE ANTAGONISTS	3 (0.3%)	6 (0.5%)
SPIRONOLACTONE	3 (0.3%)	6 (0.5%)
DIURETICS	2 (0.2%)	1 (0.1%)
ISOSORBIDE	2 (0.2%)	1 (0.1%)
OTHER POTASSIUM-SPARING AGENTS	1 (0.1%)	2 (0.2%)
TRIAMTERENE	1 (0.1%)	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	2 (0.2%)	0
HYDROCHLOROTHIAZIDE;TRIAMTERENE	2 (0.2%)	0
DRUGS FOR ACID RELATED DISORDERS	67 (5.6%)	53 (4.4%)
PROTON PUMP INHIBITORS	60 (5.0%)	46 (3.9%)
OMEPRAZOLE	38 (3.2%)	20 (1.7%)
PANTOPRAZOLE	14 (1.2%)	14 (1.2%)
ESOMEPRAZOLE	5 (0.4%)	6 (0.5%)
LANSOPRAZOLE	3 (0.3%)	2 (0.2%)
DEXLANSOPRAZOLE	0	2 (0.2%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0	2 (0.2%)
H2-RECEPTOR ANTAGONISTS	9 (0.8%)	4 (0.3%)
FAMOTIDINE	9 (0.8%)	3 (0.3%)
CIMETIDINE	0	1 (0.1%)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	2 (0.2%)	1 (0.1%)
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	1 (0.1%)	1 (0.1%)
ALMAGATE	1 (0.1%)	0
ANTACIDS WITH ANTIFLATULENTS	0	2 (0.2%)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	0	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ALUMINIUM COMPOUNDS	1 (0.1%)	0
ALUMINIUM HYDROXIDE	1 (0.1%)	0
ANTACIDS WITH SODIUM BICARBONATE	0	1 (0.1%)
SODIUM BICARBONATE	0	1 (0.1%)
CALCIUM COMPOUNDS	1 (0.1%)	0
CALCIUM CARBONATE	1 (0.1%)	0
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	0	1 (0.1%)
BISMUTH SUBSALICYLATE	0	1 (0.1%)
PSYCHOANALEPTICS	54 (4.5%)	65 (5.5%)
OTHER ANTIDEPRESSANTS	23 (1.9%)	28 (2.3%)
TRAZODONE	7 (0.6%)	7 (0.6%)
BUPROPION HYDROCHLORIDE	8 (0.7%)	3 (0.3%)
LAMOTRIGINE	7 (0.6%)	4 (0.3%)
BUPROPION	0	7 (0.6%)
DULOXETINE	2 (0.2%)	2 (0.2%)
DULOXETINE HYDROCHLORIDE	2 (0.2%)	0
VENLAFAXINE	1 (0.1%)	1 (0.1%)
VENLAFAXINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
DESVENLAFAXINE	0	1 (0.1%)
DESVENLAFAXINE SUCCINATE MONOHYDRATE	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
MIRTAZAPINE	0	1 (0.1%)
VILAZODONE HYDROCHLORIDE	1 (0.1%)	0
VORTIOXETINE HYDROBROMIDE	0	1 (0.1%)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	22 (1.8%)	22 (1.8%)
CITALOPRAM	5 (0.4%)	6 (0.5%)
SERTRALINE	4 (0.3%)	5 (0.4%)
ESCITALOPRAM OXALATE	6 (0.5%)	2 (0.2%)
FLUOXETINE	3 (0.3%)	1 (0.1%)
CITALOPRAM HYDROBROMIDE	2 (0.2%)	1 (0.1%)
ESCITALOPRAM	1 (0.1%)	2 (0.2%)
SERTRALINE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
FLUOXETINE HYDROCHLORIDE	0	2 (0.2%)
PAROXETINE	0	1 (0.1%)
CENTRALLY ACTING SYMPATHOMIMETICS	15 (1.3%)	14 (1.2%)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	9 (0.8%)	10 (0.8%)
LISDEXAMFETAMINE MESILATE	1 (0.1%)	2 (0.2%)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
AMFETAMINE;DEXAMFETAMINE	1 (0.1%)	0
ATOMOXETINE	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
LISDEXAMFETAMINE	1 (0.1%)	0
METHYLPHENIDATE	1 (0.1%)	0
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	2 (0.2%)	5 (0.4%)
AMITRIPTYLINE	2 (0.2%)	3 (0.3%)
DOXEPIN	0	1 (0.1%)
NORTRIPTYLINE	0	1 (0.1%)
ANTICHOLINESTERASES	1 (0.1%)	2 (0.2%)
DONEPEZIL	1 (0.1%)	2 (0.2%)
OTHER ANTI-DEMENTIA DRUGS	0	2 (0.2%)
MEMANTINE	0	1 (0.1%)
MEMANTINE HYDROCHLORIDE	0	1 (0.1%)
XANTHINE DERIVATIVES	0	2 (0.2%)
CAFFEINE	0	2 (0.2%)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	1 (0.1%)	0
GUANFACINE	1 (0.1%)	0
PSYCHOLEPTICS	54 (4.5%)	58 (4.9%)
BENZODIAZEPINE DERIVATIVES	18 (1.5%)	22 (1.8%)
CLONAZEPAM	5 (0.4%)	6 (0.5%)
LORAZEPAM	4 (0.3%)	7 (0.6%)
ALPRAZOLAM	5 (0.4%)	5 (0.4%)
TEMAZEPAM	3 (0.3%)	3 (0.3%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DIAZEPAM	1 (0.1%)	1 (0.1%)
BROMAZEPAM	1 (0.1%)	0
OTHER ANXIOLYTICS	15 (1.3%)	24 (2.0%)
ESCITALOPRAM	2 (0.2%)	7 (0.6%)
SERTRALINE	3 (0.3%)	4 (0.3%)
ESCITALOPRAM OXALATE	3 (0.3%)	3 (0.3%)
FLUOXETINE	0	3 (0.3%)
PAROXETINE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
SERTRALINE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
DULOXETINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
PAROXETINE	1 (0.1%)	1 (0.1%)
AMITRIPTYLINE	0	1 (0.1%)
DULOXETINE	1 (0.1%)	0
FLUOXETINE HYDROCHLORIDE	1 (0.1%)	0
LAVANDULA ANGUSTIFOLIA ESSENTIAL OIL	1 (0.1%)	0
PROPRANOLOL	0	1 (0.1%)
MELATONIN RECEPTOR AGONISTS	10 (0.8%)	6 (0.5%)
MELATONIN	10 (0.8%)	6 (0.5%)
AZASPIRODECANEDIONE DERIVATIVES	8 (0.7%)	1 (0.1%)
BUSPIRONE	7 (0.6%)	1 (0.1%)
BUSPIRONE HYDROCHLORIDE	1 (0.1%)	0

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
BENZODIAZEPINE RELATED DRUGS	5 (0.4%)	4 (0.3%)
ZOLPIDEM TARTRATE	3 (0.3%)	2 (0.2%)
ZOLPIDEM	1 (0.1%)	2 (0.2%)
ESZOPICLONE	1 (0.1%)	0
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	5 (0.4%)	1 (0.1%)
QUETIAPINE	2 (0.2%)	1 (0.1%)
QUETIAPINE FUMARATE	2 (0.2%)	0
OLANZAPINE	1 (0.1%)	0
OTHER ANTIPSYCHOTICS	3 (0.3%)	3 (0.3%)
ARIPIPRAZOLE	1 (0.1%)	3 (0.3%)
VALPROATE SEMISODIUM	2 (0.2%)	0
RISPERIDONE	1 (0.1%)	0
OTHER HYPNOTICS AND SEDATIVES	2 (0.2%)	3 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	2 (0.2%)
DOXEPIN	1 (0.1%)	1 (0.1%)
SUVOREXANT	1 (0.1%)	0
DIPHENYLMETHANE DERIVATIVES	1 (0.1%)	3 (0.3%)
HYDROXYZINE	1 (0.1%)	2 (0.2%)
HYDROXYZINE EMBONATE	0	1 (0.1%)
BARBITURATES, PLAIN	0	2 (0.2%)
BUTALBITAL	0	2 (0.2%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	2 (0.2%)	0
PROCHLORPERAZINE	2 (0.2%)	0
PSYCHOLEPTICS	0	1 (0.1%)
CANNABIDIOL	0	1 (0.1%)
COUGH AND COLD PREPARATIONS	55 (4.6%)	43 (3.6%)
EXPECTORANTS	23 (1.9%)	18 (1.5%)
GUAIFENESIN	23 (1.9%)	18 (1.5%)
OTHER COUGH SUPPRESSANTS	17 (1.4%)	9 (0.8%)
BENZONATATE	15 (1.3%)	7 (0.6%)
DROPROPIZINE	2 (0.2%)	1 (0.1%)
CLOFEDANOL	0	1 (0.1%)
OPIUM ALKALOIDS AND DERIVATIVES	10 (0.8%)	12 (1.0%)
DEXTROMETHORPHAN	4 (0.3%)	3 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (0.1%)	5 (0.4%)
CODEINE	1 (0.1%)	1 (0.1%)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
BROMPHENIRAMINE;HYDROCODONE;PSEUDOEPHEDRIN E	1 (0.1%)	0
CHLORPHENAMINE;HYDROCODONE BITARTRATE	0	1 (0.1%)
HOMATROPINE;HYDROCODONE	1 (0.1%)	0
OPIUM DERIVATIVES AND EXPECTORANTS	5 (0.4%)	9 (0.8%)
CODEINE PHOSPHATE;GUAIFENESIN	1 (0.1%)	3 (0.3%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	1 (0.1%)	2 (0.2%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	1 (0.1%)	2 (0.2%)
CODEINE;GUAIFENESIN	2 (0.2%)	0
DEXTROMETHORPHAN;GUAIFENESIN	1 (0.1%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;ETHANOL;GUAIFENESIN	0	1 (0.1%)
MUCOLYTICS	5 (0.4%)	3 (0.3%)
AMBROXOL	2 (0.2%)	1 (0.1%)
ACETYLCYSTEINE	1 (0.1%)	1 (0.1%)
BROMHEXINE	1 (0.1%)	0
BROMHEXINE HYDROCHLORIDE	0	1 (0.1%)
ERDOSTEINE	1 (0.1%)	0
COUGH AND COLD PREPARATIONS	3 (0.3%)	1 (0.1%)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
EUCALYPTUS GLOBULUS OIL;MENTHOL	1 (0.1%)	0
MENTHOL	1 (0.1%)	0
HERBAL DIAPHORETICS AND OTHER HERBAL COUGH AND COLD REMEDIES	0	1 (0.1%)
SAMBUCUS NIGRA	0	1 (0.1%)
OTHER COUGH SUPPRESSANTS AND EXPECTORANTS	1 (0.1%)	0
AMBROXOL;DROPROPIZINE	1 (0.1%)	0
THYROID THERAPY	44 (3.7%)	54 (4.5%)
THYROID HORMONES	44 (3.7%)	49 (4.1%)
LEVOTHYROXINE	26 (2.2%)	30 (2.5%)
LEVOTHYROXINE SODIUM	17 (1.4%)	19 (1.6%)
LEVOTHYROXINE;LIOTHYRONINE	2 (0.2%)	0
LIOTHYRONINE	1 (0.1%)	1 (0.1%)
LIOTHYRONINE SODIUM	1 (0.1%)	0
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0	4 (0.3%)
THIAMAZOLE	0	4 (0.3%)
IODINE THERAPY	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ASCORBIC ACID;COPPER GLUCONATE;CYANOCOBALAMIN;FERROUS GLUCONATE;FOLIC ACID;IODINE;MAGNESIUM CITRATE;MANGANESE CITRATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;SELENOMETHIONINE;TYROSINE;ZINC CITRATE	0	1 (0.1%)
MINERAL SUPPLEMENTS	45 (3.8%)	45 (3.8%)
ZINC	30 (2.5%)	32 (2.7%)
ZINC	26 (2.2%)	31 (2.6%)
ZINC SULFATE	3 (0.3%)	1 (0.1%)
ZINC ACETATE;ZINC GLUCONATE	1 (0.1%)	0
MAGNESIUM	10 (0.8%)	7 (0.6%)
MAGNESIUM	7 (0.6%)	6 (0.5%)
MAGNESIUM OXIDE	3 (0.3%)	0
MAGNESIUM CHLORIDE	0	1 (0.1%)
MAGNESIUM CITRATE	0	1 (0.1%)
MAGNESIUM MALATE	0	1 (0.1%)
POTASSIUM	7 (0.6%)	6 (0.5%)
POTASSIUM	3 (0.3%)	4 (0.3%)
POTASSIUM CHLORIDE	4 (0.3%)	2 (0.2%)
CALCIUM	3 (0.3%)	7 (0.6%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CALCIUM	3 (0.3%)	5 (0.4%)
CALCIUM CARBONATE	0	1 (0.1%)
CALCIUM CHLORIDE	0	1 (0.1%)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	2 (0.2%)	1 (0.1%)
CALCIUM CARBONATE;COLECALCIFEROL	0	1 (0.1%)
CALCIUM CITRATE;COLECALCIFEROL	1 (0.1%)	0
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1%)	0
SODIUM	2 (0.2%)	0
SODIUM	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
OTHER MINERAL PRODUCTS	1 (0.1%)	0
STRONTIUM	1 (0.1%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	60 (5.0%)	29 (2.4%)
GLUCOCORTICOIDS	60 (5.0%)	29 (2.4%)
DEXAMETHASONE	39 (3.3%)	8 (0.7%)
PREDNISONE	13 (1.1%)	12 (1.0%)
METHYLPREDNISOLONE	7 (0.6%)	6 (0.5%)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	0	3 (0.3%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (0.1%)	1 (0.1%)
BETAMETHASONE	0	1 (0.1%)
CORTISONE	1 (0.1%)	0
METHYLPREDNISOLONE ACETATE	0	1 (0.1%)
TRIAMCINOLONE ACETONIDE	0	1 (0.1%)
ANTIHISTAMINES FOR SYSTEMIC USE	34 (2.8%)	44 (3.7%)
PIPERAZINE DERIVATIVES	17 (1.4%)	19 (1.6%)
CETIRIZINE HYDROCHLORIDE	9 (0.8%)	11 (0.9%)
CETIRIZINE	8 (0.7%)	7 (0.6%)
HYDROXYZINE	0	1 (0.1%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	11 (0.9%)	11 (0.9%)
LORATADINE	7 (0.6%)	9 (0.8%)
FEXOFENADINE HYDROCHLORIDE	3 (0.3%)	2 (0.2%)
EPINASTINE	1 (0.1%)	0
AMINOALKYL ETHERS	6 (0.5%)	10 (0.8%)
DIPHENHYDRAMINE HYDROCHLORIDE	4 (0.3%)	3 (0.3%)
DOXYLAMINE SUCCINATE	1 (0.1%)	4 (0.3%)
DIPHENHYDRAMINE	1 (0.1%)	2 (0.2%)
CARBINOXAMINE	0	1 (0.1%)
PHENOTHIAZINE DERIVATIVES	2 (0.2%)	3 (0.3%)
PROMETHAZINE	2 (0.2%)	3 (0.3%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SUBSTITUTED ALKYLAMINES	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE	1 (0.1%)	0
DEXBROMPHENIRAMINE	0	1 (0.1%)
ANTIVIRALS FOR SYSTEMIC USE	40 (3.4%)	22 (1.8%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	27 (2.3%)	10 (0.8%)
REMDESIVIR	18 (1.5%)	2 (0.2%)
VALACICLOVIR HYDROCHLORIDE	5 (0.4%)	3 (0.3%)
VALACICLOVIR	3 (0.3%)	2 (0.2%)
ACICLOVIR	0	2 (0.2%)
RIBAVIRIN	0	1 (0.1%)
VALGANCICLOVIR HYDROCHLORIDE	1 (0.1%)	0
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	10 (0.8%)	10 (0.8%)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE	4 (0.3%)	6 (0.5%)
EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	2 (0.2%)	2 (0.2%)
EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE	1 (0.1%)	1 (0.1%)
ABACAVIR SULFATE;LAMIVUDINE	1 (0.1%)	0
BICTEGRAVIR;EMTRICITABINE;TENOFVIR	1 (0.1%)	0
DOLUTEGRAVIR;LAMIVUDINE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
EFAVIRENZ;EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	1 (0.1%)	0
NEURAMINIDASE INHIBITORS	1 (0.1%)	3 (0.3%)
OSELTAMIVIR	1 (0.1%)	3 (0.3%)
OTHER ANTIVIRALS	3 (0.3%)	0
BAMLANIVIMAB	2 (0.2%)	0
THYMALFASIN	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	0
AMANTADINE	1 (0.1%)	0
INTEGRASE INHIBITORS	1 (0.1%)	0
DOLUTEGRAVIR SODIUM	1 (0.1%)	0
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1%)	0
EFAVIRENZ	1 (0.1%)	0
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
ABACAVIR	0	1 (0.1%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	29 (2.4%)	25 (2.1%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	13 (1.1%)	9 (0.8%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	6 (0.5%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ETHINYLESTRADIOL;NORGESTIMATE	2 (0.2%)	4 (0.3%)
DROSPIRENONE;ETHINYLESTRADIOL	2 (0.2%)	1 (0.1%)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	0	3 (0.3%)
ETHINYLESTRADIOL;LEVONORGESTREL	2 (0.2%)	0
DROSPIRENONE;ETHINYLESTRADIOL BETADEx CLATHRATE	1 (0.1%)	0
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	6 (0.5%)	8 (0.7%)
ESTRADIOL	6 (0.5%)	6 (0.5%)
ETHINYLESTRADIOL	0	2 (0.2%)
-OXOANDROSTEN (4) DERIVATIVES	5 (0.4%)	5 (0.4%)
TESTOSTERONE	3 (0.3%)	3 (0.3%)
TESTOSTERONE CIPIONATE	2 (0.2%)	1 (0.1%)
TESTOSTERONE ENANTHATE	0	1 (0.1%)
PROGESTOGENS	2 (0.2%)	7 (0.6%)
LEVONORGESTREL	2 (0.2%)	1 (0.1%)
ETONOGESTREL	0	2 (0.2%)
MEDROXYPROGESTERONE ACETATE	0	2 (0.2%)
DROSPIRENONE	0	1 (0.1%)
NORETHISTERONE	0	1 (0.1%)
PREGNEN (4) DERIVATIVES	3 (0.3%)	1 (0.1%)
PROGESTERONE	3 (0.3%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS	1 (0.1%)	1 (0.1%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	1 (0.1%)	1 (0.1%)
ESTROGENS, COMBINATIONS WITH OTHER DRUGS	1 (0.1%)	0
BAZEDOXIFENE;ESTROGENS CONJUGATED	1 (0.1%)	0
ALL OTHER THERAPEUTIC PRODUCTS	33 (2.8%)	10 (0.8%)
MEDICAL GASES	32 (2.7%)	8 (0.7%)
OXYGEN	32 (2.7%)	8 (0.7%)
OTHER THERAPEUTIC PRODUCTS	1 (0.1%)	2 (0.2%)
CHLOROPHYLL	0	1 (0.1%)
DIPENTEN	1 (0.1%)	0
HOMEOPATHICS NOS	0	1 (0.1%)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA	1 (0.1%)	0
SODIUM ZIRCONIUM CYCLOSILICATE	1 (0.1%)	0
NASAL PREPARATIONS	17 (1.4%)	21 (1.8%)
CORTICOSTEROIDS	8 (0.7%)	13 (1.1%)
FLUTICASONE PROPIONATE	4 (0.3%)	7 (0.6%)
FLUTICASONE	4 (0.3%)	2 (0.2%)
BUDESONIDE	0	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE	0	1 (0.1%)
TRIAMCINOLONE ACETONIDE	0	1 (0.1%)
SYMPATHOMIMETICS	4 (0.3%)	4 (0.3%)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (0.2%)	1 (0.1%)
PSEUDOEPHEDRINE	0	2 (0.2%)
BROMPHENIRAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
PHENYLEPHRINE	1 (0.1%)	0
PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.1%)
SYMPATHOMIMETICS, PLAIN	3 (0.3%)	2 (0.2%)
OXYMETAZOLINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
OXYMETAZOLINE	0	1 (0.1%)
PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
TETRYZOLINE	1 (0.1%)	0
OTHER NASAL PREPARATIONS	2 (0.2%)	2 (0.2%)
IPRATROPIUM BROMIDE	0	1 (0.1%)
MUPIROCIN	1 (0.1%)	0
OTHER NASAL PREPARATIONS	1 (0.1%)	0
SODIUM CHLORIDE;XYLITOL	0	1 (0.1%)
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
AZELASTINE	1 (0.1%)	1 (0.1%)
UROLOGICALS	18 (1.5%)	11 (0.9%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	11 (0.9%)	9 (0.8%)
TAMSULOSIN	9 (0.8%)	4 (0.3%)
TAMSULOSIN HYDROCHLORIDE	1 (0.1%)	4 (0.3%)
ALFUZOSIN	0	1 (0.1%)
TERAZOSIN	1 (0.1%)	0
DRUGS USED IN ERECTILE DYSFUNCTION	4 (0.3%)	0
SILDENAFIL	2 (0.2%)	0
SILDENAFIL CITRATE	1 (0.1%)	0
TADALAFIL	1 (0.1%)	0
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	2 (0.2%)	2 (0.2%)
FINASTERIDE	2 (0.2%)	2 (0.2%)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	3 (0.3%)	0
DULOXETINE HYDROCHLORIDE	1 (0.1%)	0
OXYBUTYNIN	1 (0.1%)	0
OXYBUTYNIN HYDROCHLORIDE	1 (0.1%)	0
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	0	1 (0.1%)
TADALAFIL	0	1 (0.1%)
URINARY CONCREMENT SOLVENTS	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SODIUM BICARBONATE	1 (0.1%)	0
CARDIAC THERAPY	16 (1.3%)	9 (0.8%)
ORGANIC NITRATES	4 (0.3%)	3 (0.3%)
GLYCERYL TRINITRATE	3 (0.3%)	2 (0.2%)
ISOSORBIDE DINITRATE	1 (0.1%)	0
ISOSORBIDE MONONITRATE	0	1 (0.1%)
ADRENERGIC AND DOPAMINERGIC AGENTS	2 (0.2%)	4 (0.3%)
EPINEPHRINE	0	4 (0.3%)
PHENYLEPHRINE	2 (0.2%)	0
ANTIARRHYTHMICS, CLASS III	5 (0.4%)	0
AMIODARONE	3 (0.3%)	0
DOFETILIDE	2 (0.2%)	0
OTHER CARDIAC PREPARATIONS	3 (0.3%)	1 (0.1%)
UBIDECARENONE	3 (0.3%)	0
IVABRADINE HYDROCHLORIDE	0	1 (0.1%)
DIGITALIS GLYCOSIDES	2 (0.2%)	1 (0.1%)
DIGOXIN	2 (0.2%)	1 (0.1%)
OTHER VASODILATORS USED IN CARDIAC DISEASES	1 (0.1%)	0
SACUBITRIL	1 (0.1%)	0
MUSCLE RELAXANTS	11 (0.9%)	13 (1.1%)
OTHER CENTRALLY ACTING AGENTS	10 (0.8%)	10 (0.8%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CYCLOBENZAPRINE	4 (0.3%)	5 (0.4%)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (0.2%)	4 (0.3%)
TIZANIDINE	3 (0.3%)	0
TIZANIDINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
CARBAMIC ACID ESTERS	0	3 (0.3%)
METHOCARBAMOL	0	3 (0.3%)
OTHER QUATERNARY AMMONIUM COMPOUNDS	1 (0.1%)	0
VECURONIUM BROMIDE	1 (0.1%)	0
ANTIGOUT PREPARATIONS	9 (0.8%)	14 (1.2%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	6 (0.5%)	11 (0.9%)
ALLOPURINOL	6 (0.5%)	11 (0.9%)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	3 (0.3%)	3 (0.3%)
COLCHICINE	3 (0.3%)	3 (0.3%)
PREPARATIONS INCREASING URIC ACID EXCRETION	0	1 (0.1%)
PROBENECID	0	1 (0.1%)
IMMUNOSUPPRESSANTS	9 (0.8%)	14 (1.2%)
OTHER IMMUNOSUPPRESSANTS	6 (0.5%)	7 (0.6%)
HYDROXYCHLOROQUINE	4 (0.3%)	4 (0.3%)
METHOTREXATE	2 (0.2%)	3 (0.3%)
AZATHIOPRINE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SELECTIVE IMMUNOSUPPRESSANTS	3 (0.3%)	3 (0.3%)
APREMILAST	1 (0.1%)	0
BARICITINIB	1 (0.1%)	0
BELIMUMAB	0	1 (0.1%)
MYCOPHENOLATE MOFETIL	1 (0.1%)	0
SIROLIMUS	0	1 (0.1%)
UPADACITINIB	0	1 (0.1%)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	0	3 (0.3%)
ADALIMUMAB	0	2 (0.2%)
ETANERCEPT	0	1 (0.1%)
CALCINEURIN INHIBITORS	1 (0.1%)	0
TACROLIMUS	1 (0.1%)	0
INTERLEUKIN INHIBITORS	0	1 (0.1%)
BRODALUMAB	0	1 (0.1%)
ANTIEMETICS AND ANTINAUSEANTS	12 (1.0%)	6 (0.5%)
SEROTONIN (5HT3) ANTAGONISTS	9 (0.8%)	3 (0.3%)
ONDANSETRON	9 (0.8%)	3 (0.3%)
OTHER ANTIEMETICS	4 (0.3%)	3 (0.3%)
PROMETHAZINE	3 (0.3%)	2 (0.2%)
DIFENIDOL	0	1 (0.1%)
MECLOZINE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	0
ANTIEPILEPTICS	8 (0.7%)	9 (0.8%)
OTHER ANTIEPILEPTICS	4 (0.3%)	3 (0.3%)
LEVETIRACETAM	3 (0.3%)	1 (0.1%)
GABAPENTIN	0	1 (0.1%)
LACOSAMIDE	0	1 (0.1%)
TOPIRAMATE	1 (0.1%)	0
BENZODIAZEPINE DERIVATIVES	2 (0.2%)	1 (0.1%)
CLOBAZAM	1 (0.1%)	0
DIAZEPAM	1 (0.1%)	0
LORAZEPAM	0	1 (0.1%)
CARBOXAMIDE DERIVATIVES	2 (0.2%)	1 (0.1%)
OXCARBAZEPINE	2 (0.2%)	1 (0.1%)
FATTY ACID DERIVATIVES	1 (0.1%)	2 (0.2%)
TIAGABINE	0	1 (0.1%)
VALPROATE SEMISODIUM	1 (0.1%)	0
VALPROATE SODIUM	0	1 (0.1%)
HYDANTOIN DERIVATIVES	0	2 (0.2%)
PHENYTOIN	0	1 (0.1%)
PHENYTOIN SODIUM	0	1 (0.1%)
ANTIANEMIC PREPARATIONS	11 (0.9%)	4 (0.3%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
IRON BIVALENT, ORAL PREPARATIONS	8 (0.7%)	2 (0.2%)
FERROUS SULFATE	3 (0.3%)	1 (0.1%)
IRON	3 (0.3%)	1 (0.1%)
ASCORBIC ACID;FERROUS FUMARATE	1 (0.1%)	0
FERROUS GLUCONATE	1 (0.1%)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	5 (0.4%)	2 (0.2%)
VITAMIN B12 NOS	4 (0.3%)	2 (0.2%)
CYANOCOBALAMIN	1 (0.1%)	0
IRON IN OTHER COMBINATIONS	0	1 (0.1%)
FERRIC AMMONIUM CITRATE;FOLIC ACID;VITAMIN B12 NOS	0	1 (0.1%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	12 (1.0%)	3 (0.3%)
ELECTROLYTE SOLUTIONS	10 (0.8%)	2 (0.2%)
SODIUM CHLORIDE	10 (0.8%)	2 (0.2%)
MAGNESIUM SULFATE	2 (0.2%)	0
POTASSIUM CHLORIDE	2 (0.2%)	0
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1 (0.1%)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	3 (0.3%)	0
GLUCOSE;SODIUM CHLORIDE	1 (0.1%)	0
POTASSIUM	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SODIUM CHLORIDE	1 (0.1%)	0
SOLUTIONS FOR PARENTERAL NUTRITION	0	1 (0.1%)
GLUCOSE	0	1 (0.1%)
OPHTHALMOLOGICALS	10 (0.8%)	3 (0.3%)
OTHER OPHTHALMOLOGICALS	4 (0.3%)	2 (0.2%)
LIFITEGRAST	2 (0.2%)	0
ARTIFICIAL TEARS [UMBRELLA TERM]	0	1 (0.1%)
ASCORBIC ACID;TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC	1 (0.1%)	0
CARMELLOSE	1 (0.1%)	0
CARMELLOSE SODIUM	1 (0.1%)	0
HYPROMELLOSE	0	1 (0.1%)
PROSTAGLANDIN ANALOGUES	4 (0.3%)	0
LATANOPROST	4 (0.3%)	0
ANTIBIOTICS	1 (0.1%)	1 (0.1%)
ERYTHROMYCIN	1 (0.1%)	1 (0.1%)
BETA BLOCKING AGENTS	2 (0.2%)	0
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	1 (0.1%)	0
TIMOLOL	1 (0.1%)	0
ANTIINFLAMMATORY AGENTS, NON-STEROIDS	0	1 (0.1%)
KETOROLAC	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
VACCINES	5 (0.4%)	8 (0.7%)
OTHER VIRAL VACCINES	5 (0.4%)	6 (0.5%)
COVID-19 VACCINE	5 (0.4%)	6 (0.5%)
INFLUENZA VACCINES	0	2 (0.2%)
INFLUENZA VACCINE	0	1 (0.1%)
INFLUENZA VACCINE INACT SPLIT 4V	0	1 (0.1%)
ANTIHYPERTENSIVES	6 (0.5%)	5 (0.4%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	2 (0.2%)	3 (0.3%)
DOXAZOSIN	0	2 (0.2%)
PRAZOSIN	1 (0.1%)	1 (0.1%)
DOXAZOSIN MESILATE	1 (0.1%)	0
HYDRAZINOPHTHALAZINE DERIVATIVES	3 (0.3%)	1 (0.1%)
HYDRALAZINE	3 (0.3%)	1 (0.1%)
IMIDAZOLINE RECEPTOR AGONISTS	2 (0.2%)	1 (0.1%)
CLONIDINE	1 (0.1%)	1 (0.1%)
GUANFACINE HYDROCHLORIDE	1 (0.1%)	0
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	5 (0.4%)	6 (0.5%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0.1%)	5 (0.4%)
TRIAMCINOLONE	0	3 (0.3%)
TRIAMCINOLONE ACETONIDE	0	2 (0.2%)
DESONIDE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CORTICOSTEROIDS, POTENT (GROUP III)	3 (0.3%)	1 (0.1%)
HYDROCORTISONE	1 (0.1%)	1 (0.1%)
BETAMETHASONE	1 (0.1%)	0
ULOBETASOL	1 (0.1%)	0
CORTICOSTEROIDS, WEAK (GROUP I)	1 (0.1%)	0
HYDROCORTISONE	1 (0.1%)	0
OTHER GYNECOLOGICALS	6 (0.5%)	5 (0.4%)
INTRAUTERINE CONTRACEPTIVES	4 (0.3%)	5 (0.4%)
LEVONORGESTREL	4 (0.3%)	4 (0.3%)
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (0.1%)
INTRAVAGINAL CONTRACEPTIVES	1 (0.1%)	0
ETHINYLESTRADIOL;ETONOGESTREL	1 (0.1%)	0
OTHER GYNECOLOGICALS	1 (0.1%)	0
METHOTREXATE	1 (0.1%)	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.3%)	6 (0.5%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.3%)	6 (0.5%)
SAMBUCUS NIGRA	0	2 (0.2%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.1%)	1 (0.1%)
WITHANIA SOMNIFERA	0	2 (0.2%)
BACOPA MONNIERI	1 (0.1%)	0
CURCUMA LONGA RHIZOME	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
MALUS SPP. VINEGAR EXTRACT	1 (0.1%)	0
MITRAGYNA SPECIOSA	0	1 (0.1%)
PRUNUS CERASUS	1 (0.1%)	0
TRIGONELLA FOENUM-GRAECUM	0	1 (0.1%)
VALERIANA OFFICINALIS ROOT	0	1 (0.1%)
ANTI-PARKINSON DRUGS	5 (0.4%)	4 (0.3%)
DOPAMINE AGONISTS	4 (0.3%)	2 (0.2%)
PRAMIPEXOLE	2 (0.2%)	0
ROPINIROLE	1 (0.1%)	1 (0.1%)
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	0	1 (0.1%)
ROPINIROLE HYDROCHLORIDE	1 (0.1%)	0
DOPA AND DOPA DERIVATIVES	2 (0.2%)	2 (0.2%)
CARBIDOPA	2 (0.2%)	1 (0.1%)
CARBIDOPA;LEVODOPA	0	1 (0.1%)
LEVODOPA	1 (0.1%)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	5 (0.4%)	4 (0.3%)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	5 (0.4%)	4 (0.3%)
PROBIOTICS NOS	2 (0.2%)	2 (0.2%)
QUERCETIN	2 (0.2%)	2 (0.2%)
ASTAXANTHIN	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER NERVOUS SYSTEM DRUGS	3 (0.3%)	6 (0.5%)
OTHER NERVOUS SYSTEM DRUGS	0	4 (0.3%)
GABAPENTIN	0	3 (0.3%)
EDARAVONE	0	1 (0.1%)
RILUZOLE	0	1 (0.1%)
ANTIVERTIGO PREPARATIONS	2 (0.2%)	0
MECLOZINE	1 (0.1%)	0
MECLOZINE HYDROCHLORIDE	1 (0.1%)	0
DRUGS USED IN NICOTINE DEPENDENCE	1 (0.1%)	0
BUPROPION	1 (0.1%)	0
DRUGS USED IN OPIOID DEPENDENCE	0	1 (0.1%)
NALTREXONE	0	1 (0.1%)
OTHER PARASYMPATHOMIMETICS	0	1 (0.1%)
CEVIMELINE	0	1 (0.1%)
DRUGS FOR CONSTIPATION	4 (0.3%)	4 (0.3%)
SOFTENERS, EMOLLIENTS	3 (0.3%)	2 (0.2%)
DOCUSATE SODIUM	2 (0.2%)	2 (0.2%)
DOCUSATE	1 (0.1%)	0
BULK-FORMING LAXATIVES	0	2 (0.2%)
METHYLCELLULOSE	0	1 (0.1%)
POLYCARBOPHIL	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OSMOTICALLY ACTING LAXATIVES	2 (0.2%)	0
MAGNESIUM HYDROXIDE	2 (0.2%)	0
LACTULOSE	1 (0.1%)	0
CONTACT LAXATIVES	1 (0.1%)	0
BISACODYL	1 (0.1%)	0
ANTHELMINTICS	5 (0.4%)	1 (0.1%)
AVERMECTINES	5 (0.4%)	1 (0.1%)
IVERMECTIN	5 (0.4%)	1 (0.1%)
ANTIDIARRHEALS, INTESTINAL	4 (0.3%)	2 (0.2%)
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
ANTIDIARRHEAL MICROORGANISMS	2 (0.2%)	1 (0.1%)
BIFIDOBACTERIUM LACTIS;INULIN;LACTOBACILLUS	1 (0.1%)	0
ACIDOPHILUS;LACTOBACILLUS		
PARACASEI;SACCHAROMYCES		
BOULARDII;TRANS-GALACTOOLIGOSACCHARIDE		
PROBIOTICS NOS	1 (0.1%)	0
SACCHAROMYCES BOULARDII	0	1 (0.1%)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1%)	1 (0.1%)
MESALAZINE	1 (0.1%)	1 (0.1%)
ANTIPROPULSIVES	0	1 (0.1%)
LOPERAMIDE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ORAL REHYDRATION SALT FORMULATIONS	1 (0.1%)	0
ELECTROLYTES NOS;GLUCOSE	1 (0.1%)	0
IMMUNE SERA AND IMMUNOGLOBULINS	6 (0.5%)	0
SPECIFIC IMMUNOGLOBULINS	6 (0.5%)	0
HYPERIMMUNE PLASMA COVID-19	6 (0.5%)	0
ANTINEOPLASTIC AGENTS	3 (0.3%)	2 (0.2%)
MONOCLONAL ANTIBODIES	2 (0.2%)	1 (0.1%)
RITUXIMAB	2 (0.2%)	0
BEVACIZUMAB	0	1 (0.1%)
BRUTON'S TYROSINE KINASE (BTK) INHIBITORS	0	1 (0.1%)
IBRUTINIB	0	1 (0.1%)
CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS	1 (0.1%)	0
PALBOCICLIB	1 (0.1%)	0
ENDOCRINE THERAPY	2 (0.2%)	3 (0.3%)
AROMATASE INHIBITORS	2 (0.2%)	2 (0.2%)
LETROZOLE	2 (0.2%)	0
,3'-DIINDOLYLMET HANE	0	1 (0.1%)
ANASTROZOLE	0	1 (0.1%)
ANTI-ESTROGENS	0	1 (0.1%)
TAMOXIFEN	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	3 (0.3%)	1 (0.1%)
OTHER CHEMOTHERAPEUTICS	2 (0.2%)	0
METRONIDAZOLE	2 (0.2%)	0
ANTIVIRALS	0	1 (0.1%)
IMIQUIMOD	0	1 (0.1%)
OTHER ANTIBIOTICS FOR TOPICAL USE	1 (0.1%)	0
BACITRACIN	1 (0.1%)	0
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	4 (0.3%)	0
PROPULSIVES	2 (0.2%)	0
CINITAPRIDE	1 (0.1%)	0
METOCLOPRAMIDE	1 (0.1%)	0
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	2 (0.2%)	0
DICYCLOVERINE	1 (0.1%)	0
TRIMEBUTINE	1 (0.1%)	0
DRUGS FOR TREATMENT OF BONE DISEASES	1 (0.1%)	3 (0.3%)
BISPHOSPHONATES	1 (0.1%)	1 (0.1%)
ALENDRONATE SODIUM	1 (0.1%)	1 (0.1%)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	0	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DENOSUMAB	0	2 (0.2%)
ANTI-ACNE PREPARATIONS	1 (0.1%)	2 (0.2%)
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE	0	1 (0.1%)
DAPSONE	0	1 (0.1%)
RETINOIDS FOR TOPICAL USE IN ACNE	1 (0.1%)	0
TRETINOIN	1 (0.1%)	0
RETINOIDS FOR TREATMENT OF ACNE	0	1 (0.1%)
ISOTRETINOIN	0	1 (0.1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	2 (0.2%)	1 (0.1%)
CENTRALLY ACTING ANTIOBESITY PRODUCTS	2 (0.2%)	1 (0.1%)
PHENETERMINE	2 (0.2%)	1 (0.1%)
IMMUNOSTIMULANTS	3 (0.3%)	0
HERBAL IMMUNOMODULATORS	2 (0.2%)	0
ASCORBIC ACID;CALCIUM;CORDYCEPS SINENSIS;GANODERMA LUCIDUM;GRIFOLA FRONDOSA;HERICIUM ERINACEUS;VITAMIN D NOS	1 (0.1%)	0
ECHINACEA SPP.	1 (0.1%)	0
COLONY STIMULATING FACTORS	1 (0.1%)	0
FILGRASTIM	1 (0.1%)	0
OTHER DERMATOLOGICAL PREPARATIONS	0	3 (0.3%)
OTHER DERMATOLOGICALS	0	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DICLOFENAC SODIUM	0	1 (0.1%)
FINASTERIDE	0	1 (0.1%)
ANTIHYDROTICS	0	1 (0.1%)
GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (0.1%)	1 (0.1%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ASCORBIC ACID	0	1 (0.1%)
OTHER NON-THERAPEUTIC AUXILIARY PRODUCTS	1 (0.1%)	0
POLYETHYLENE	1 (0.1%)	0
ANESTHETICS	2 (0.2%)	0
OPIOID ANESTHETICS	2 (0.2%)	0
FENTANYL	2 (0.2%)	0
OTHER GENERAL ANESTHETICS	1 (0.1%)	0
PROPOFOL	1 (0.1%)	0
ANTIFUNGALS FOR DERMATOLOGICAL USE	0	2 (0.2%)
ANTIFUNGALS FOR SYSTEMIC USE	0	1 (0.1%)
TERBINAFINE	0	1 (0.1%)
OTHER ANTIFUNGALS FOR TOPICAL USE	0	1 (0.1%)
TOLNAFTATE	0	1 (0.1%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	2 (0.2%)	0

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.1%)	0
AMINO ACIDS NOS;ANIMAL UNSPECIFIED;ASCORBIC ACID;CYANOCOBALAMIN;HERBAL NOS;MANGANESE;PHOSPHORUS;RETINOL PALMITATE;TOCOPHEROL	1 (0.1%)	0
QUININE AND DERIVATIVES	1 (0.1%)	0
QUININE	1 (0.1%)	0
TONICS	1 (0.1%)	1 (0.1%)
HERBAL TONICS, OTHER	0	1 (0.1%)
MORINGA OLEIFERA	0	1 (0.1%)
TONICS	1 (0.1%)	0
DIETARY SUPPLEMENT	1 (0.1%)	0
Uncoded	2 (0.2%)	0
Uncoded	2 (0.2%)	0
ADRENAL CORTICAL EXTRACT;ADRENAL GLAND;CALCIUM PANTOTHENATE;CORDYCEPS SINENSIS MYCELIUM;ELEUTHEROCOCCUS SPP.;WITHANIA SOMNIFERA ROOT	1 (0.1%)	0
BLINDED THERAPY	1 (0.1%)	0
VASOPROTECTIVES	0	2 (0.2%)
BIOFLAVONOIDS	0	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ALKA 4-COMPLEX;DIOSMIN	0	1 (0.1%)
DIOSMIN	0	1 (0.1%)
ANABOLIC AGENTS FOR SYSTEMIC USE	0	1 (0.1%)
ANDROSTAN DERIVATIVES	0	1 (0.1%)
PRASTERONE	0	1 (0.1%)
ANTIHEMORRHAGICS	1 (0.1%)	0
VITAMIN K	1 (0.1%)	0
VITAMIN K NOS	1 (0.1%)	0
ANTIMYCOTICS FOR SYSTEMIC USE	1 (0.1%)	0
TRIAZOLE DERIVATIVES	1 (0.1%)	0
FLUCONAZOLE	1 (0.1%)	0
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	1 (0.1%)	0
ANTIHTAMINES FOR TOPICAL USE	1 (0.1%)	0
DIPHENHYDRAMINE	1 (0.1%)	0
ANTIPSORIATICS	1 (0.1%)	0
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (0.1%)	0
CALCIPOTRIOL	1 (0.1%)	0
DIGESTIVES, INCL. ENZYMES	0	1 (0.1%)
HERBAL DIGESTIVES, OTHER	0	1 (0.1%)
SILYBUM MARIANUM	0	1 (0.1%)

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Table 21.1. Concomitant medications day 1 to day 29
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
EMOLLIENTS AND PROTECTIVES	1 (0.1%)	0
ZINC PRODUCTS	1 (0.1%)	0
MENTHOL;ZINC OXIDE	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
PANCREATIC HORMONES	1 (0.1%)	0
GLYCOGENOLYTIC HORMONES	1 (0.1%)	0
GLUCAGON	1 (0.1%)	0
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	0	1 (0.1%)
VASOPRESSIN AND ANALOGUES	0	1 (0.1%)
DESMOPRESSIN	0	1 (0.1%)
THROAT PREPARATIONS	0	1 (0.1%)
ANTISEPTICS	0	1 (0.1%)
PHENOL	0	1 (0.1%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0	1 (0.1%)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	0	1 (0.1%)
DICLOFENAC	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant medication	94 (7.9%)	61 (5.1%)
ANTIBACTERIALS FOR SYSTEMIC USE	41 (3.4%)	29 (2.4%)
MACROLIDES	21 (1.8%)	15 (1.3%)
AZITHROMYCIN	20 (1.7%)	15 (1.3%)
ERYTHROMYCIN	1 (0.1%)	0
THIRD-GENERATION CEPHALOSPORINS	14 (1.2%)	10 (0.8%)
CEFTRIAZONE	8 (0.7%)	3 (0.3%)
CEFTRIAZONE SODIUM	4 (0.3%)	3 (0.3%)
CEFDINIR	3 (0.3%)	3 (0.3%)
CEFPODOXIME PROXETIL	0	1 (0.1%)
FLUOROQUINOLONES	3 (0.3%)	3 (0.3%)
LEVOFLOXACIN	2 (0.2%)	2 (0.2%)
CIPROFLOXACIN	1 (0.1%)	1 (0.1%)
TETRACYCLINES	4 (0.3%)	2 (0.2%)
DOXYCYCLINE	4 (0.3%)	2 (0.2%)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	2 (0.2%)	1 (0.1%)
AMOXICILLIN;CLAVULANIC ACID	1 (0.1%)	1 (0.1%)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	1 (0.1%)	0
PENICILLINS WITH EXTENDED SPECTRUM	2 (0.2%)	1 (0.1%)
AMOXICILLIN	2 (0.2%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIBACTERIALS FOR SYSTEMIC USE	1 (0.1%)	1 (0.1%)
BROAD SPECTRUM ANTIBIOTICS	1 (0.1%)	0
PENICILLIN NOS	0	1 (0.1%)
NITROFURAN DERIVATIVES	0	2 (0.2%)
NITROFURANTOIN	0	2 (0.2%)
CARBAPENEMS	1 (0.1%)	0
MEROPENEM	1 (0.1%)	0
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	0	1 (0.1%)
SULFAMETHOXAZOLE;TRIMETHOPRIM	0	1 (0.1%)
FIRST-GENERATION CEPHALOSPORINS	0	1 (0.1%)
CEFALEXIN	0	1 (0.1%)
FOURTH-GENERATION CEPHALOSPORINS	0	1 (0.1%)
CEFEPIME	0	1 (0.1%)
GLYCOPEPTIDE ANTIBACTERIALS	0	1 (0.1%)
VANCOMYCIN	0	1 (0.1%)
INTERMEDIATE-ACTING SULFONAMIDES	1 (0.1%)	0
SULFAMETHOXAZOLE	1 (0.1%)	0
LINCOSAMIDES	0	1 (0.1%)
LINCOMYCIN	0	1 (0.1%)
CORTICOSTEROIDS FOR SYSTEMIC USE	44 (3.7%)	20 (1.7%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
GLUCOCORTICOIDS	44 (3.7%)	20 (1.7%)
DEXAMETHASONE	32 (2.7%)	6 (0.5%)
PREDNISONE	8 (0.7%)	9 (0.8%)
METHYLPREDNISOLONE	3 (0.3%)	4 (0.3%)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	0	3 (0.3%)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (0.1%)	1 (0.1%)
BETAMETHASONE	0	1 (0.1%)
ALL OTHER THERAPEUTIC PRODUCTS	29 (2.4%)	7 (0.6%)
MEDICAL GASES	29 (2.4%)	7 (0.6%)
OXYGEN	29 (2.4%)	7 (0.6%)
COUGH AND COLD PREPARATIONS	16 (1.3%)	8 (0.7%)
OTHER COUGH SUPPRESSANTS	8 (0.7%)	4 (0.3%)
BENZONATATE	8 (0.7%)	3 (0.3%)
CLOFEDANOL	0	1 (0.1%)
OPIUM ALKALOIDS AND DERIVATIVES	5 (0.4%)	3 (0.3%)
DEXTROMETHORPHAN	2 (0.2%)	1 (0.1%)
CODEINE	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE;HYDROCODONE;PSEUDOEPHEDRIN E	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	0	1 (0.1%)
HOMATROPINE;HYDROCODONE	1 (0.1%)	0
EXPECTORANTS	5 (0.4%)	1 (0.1%)
GUAIFENESIN	5 (0.4%)	1 (0.1%)
OPIUM DERIVATIVES AND EXPECTORANTS	1 (0.1%)	2 (0.2%)
CODEINE PHOSPHATE;GUAIFENESIN	0	1 (0.1%)
CODEINE;GUAIFENESIN	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;ETHANOL;GUAIFENESIN	0	1 (0.1%)
ANALGESICS	11 (0.9%)	10 (0.8%)
ANILIDES	10 (0.8%)	6 (0.5%)
PARACETAMOL	10 (0.8%)	4 (0.3%)
CHLORPHENAMINE MALEATE;PARACETAMOL	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	0	2 (0.2%)
CODEINE PHOSPHATE;PARACETAMOL	0	1 (0.1%)
HYDROCODONE BITARTRATE;PARACETAMOL	0	1 (0.1%)
OTHER OPIOIDS	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
TRAMADOL	1 (0.1%)	1 (0.1%)
SALICYLIC ACID AND DERIVATIVES	0	1 (0.1%)
ACETYLSALICYLIC ACID	0	1 (0.1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	16 (1.3%)	4 (0.3%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	14 (1.2%)	2 (0.2%)
SALBUTAMOL	10 (0.8%)	1 (0.1%)
SALBUTAMOL SULFATE	4 (0.3%)	1 (0.1%)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	1 (0.1%)	2 (0.2%)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	0	1 (0.1%)
IPRATROPIUM BROMIDE;SALBUTAMOL	0	1 (0.1%)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	1 (0.1%)	0
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1%)	0
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	1 (0.1%)	0
ANTICHOLINERGICS	1 (0.1%)	0
IPRATROPIUM	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	16 (1.3%)	3 (0.3%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	15 (1.3%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
REMDESIVIR	15 (1.3%)	2 (0.2%)
NEURAMINIDASE INHIBITORS	0	1 (0.1%)
OSELTAMIVIR	0	1 (0.1%)
OTHER ANTIVIRALS	1 (0.1%)	0
BAMLANIVIMAB	1 (0.1%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	6 (0.5%)	6 (0.5%)
PROPIONIC ACID DERIVATIVES	5 (0.4%)	6 (0.5%)
IBUPROFEN	5 (0.4%)	4 (0.3%)
NAPROXEN	0	2 (0.2%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	1 (0.1%)	0
KETOROLAC TROMETHAMINE	1 (0.1%)	0
ANTITHROMBOTIC AGENTS	8 (0.7%)	3 (0.3%)
HEPARIN GROUP	7 (0.6%)	2 (0.2%)
ENOXAPARIN	6 (0.5%)	0
ENOXAPARIN SODIUM	0	2 (0.2%)
HEPARIN SODIUM	1 (0.1%)	0
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	2 (0.2%)	1 (0.1%)
ACETYLSALICYLIC ACID	1 (0.1%)	1 (0.1%)
EPOPSTENOL	1 (0.1%)	0
PRASUGREL	0	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
APIXABAN	0	1 (0.1%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	8 (0.7%)	3 (0.3%)
ELECTROLYTE SOLUTIONS	7 (0.6%)	2 (0.2%)
SODIUM CHLORIDE	7 (0.6%)	2 (0.2%)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
SOLUTIONS FOR PARENTERAL NUTRITION	0	1 (0.1%)
GLUCOSE	0	1 (0.1%)
DRUGS FOR ACID RELATED DISORDERS	7 (0.6%)	4 (0.3%)
H2-RECEPTOR ANTAGONISTS	3 (0.3%)	2 (0.2%)
FAMOTIDINE	3 (0.3%)	2 (0.2%)
PROTON PUMP INHIBITORS	4 (0.3%)	1 (0.1%)
PANTOPRAZOLE	2 (0.2%)	1 (0.1%)
OMEPRAZOLE	2 (0.2%)	0
ANTACIDS WITH ANTIFLATULENTS	0	2 (0.2%)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	0	2 (0.2%)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	1 (0.1%)	1 (0.1%)
ALMAGATE	1 (0.1%)	0
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
MINERAL SUPPLEMENTS	7 (0.6%)	3 (0.3%)
ZINC	4 (0.3%)	1 (0.1%)
ZINC SULFATE	3 (0.3%)	1 (0.1%)
ZINC	1 (0.1%)	0
POTASSIUM	1 (0.1%)	2 (0.2%)
POTASSIUM	0	2 (0.2%)
POTASSIUM CHLORIDE	1 (0.1%)	0
MAGNESIUM	1 (0.1%)	1 (0.1%)
MAGNESIUM	0	1 (0.1%)
MAGNESIUM OXIDE	1 (0.1%)	0
SODIUM	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
ANTIEMETICS AND ANTINAUSEANTS	6 (0.5%)	3 (0.3%)
SEROTONIN (5HT3) ANTAGONISTS	5 (0.4%)	2 (0.2%)
ONDANSETRON	5 (0.4%)	2 (0.2%)
OTHER ANTIEMETICS	1 (0.1%)	1 (0.1%)
PROMETHAZINE	1 (0.1%)	1 (0.1%)
ANTI-HISTAMINES FOR SYSTEMIC USE	5 (0.4%)	4 (0.3%)
AMINOALKYL ETHERS	2 (0.2%)	2 (0.2%)
DIPHENHYDRAMINE	1 (0.1%)	1 (0.1%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PHENOTHIAZINE DERIVATIVES	1 (0.1%)	1 (0.1%)
PROMETHAZINE	1 (0.1%)	1 (0.1%)
PIPERAZINE DERIVATIVES	1 (0.1%)	1 (0.1%)
CETIRIZINE	1 (0.1%)	0
HYDROXYZINE	0	1 (0.1%)
SUBSTITUTED ALKYLAMINES	1 (0.1%)	0
BROMPHENIRAMINE	1 (0.1%)	0
VITAMINS	6 (0.5%)	2 (0.2%)
ASCORBIC ACID (VITAMIN C), PLAIN	4 (0.3%)	1 (0.1%)
ASCORBIC ACID	4 (0.3%)	1 (0.1%)
VITAMIN D AND ANALOGUES	2 (0.2%)	1 (0.1%)
COLECALCIFEROL	2 (0.2%)	1 (0.1%)
MULTIVITAMINS, PLAIN	1 (0.1%)	1 (0.1%)
VITAMINS NOS	1 (0.1%)	1 (0.1%)
COMBINATIONS OF VITAMINS	1 (0.1%)	0
ASCORBIC ACID;VITAMIN D NOS	1 (0.1%)	0
VITAMIN B1, PLAIN	0	1 (0.1%)
THIAMINE	0	1 (0.1%)
DIURETICS	1 (0.1%)	3 (0.3%)
SULFONAMIDES, PLAIN	1 (0.1%)	2 (0.2%)
FUROSEMIDE	1 (0.1%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ALDOSTERONE ANTAGONISTS	0	1 (0.1%)
SPIRONOLACTONE	0	1 (0.1%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1%)	2 (0.2%)
CORTICOSTEROIDS, POTENT (GROUP III)	1 (0.1%)	1 (0.1%)
HYDROCORTISONE	1 (0.1%)	1 (0.1%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	0	1 (0.1%)
TRIAMCINOLONE	0	1 (0.1%)
DRUGS USED IN DIABETES	2 (0.2%)	1 (0.1%)
BIGUANIDES	1 (0.1%)	1 (0.1%)
METFORMIN	1 (0.1%)	1 (0.1%)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (0.1%)	0
INSULIN LISPRO	1 (0.1%)	0
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	1 (0.1%)	0
INSULIN GLARGINE	1 (0.1%)	0
IMMUNE SERA AND IMMUNOGLOBULINS	3 (0.3%)	0
SPECIFIC IMMUNOGLOBULINS	3 (0.3%)	0
HYPERIMMUNE PLASMA COVID-19	3 (0.3%)	0
MUSCLE RELAXANTS	3 (0.3%)	0
OTHER CENTRALLY ACTING AGENTS	2 (0.2%)	0
CYCLOBENZAPRINE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (0.1%)	0
OTHER QUATERNARY AMMONIUM COMPOUNDS	1 (0.1%)	0
VECURONIUM BROMIDE	1 (0.1%)	0
PSYCHOLEPTICS	2 (0.2%)	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	2 (0.2%)	0
LORAZEPAM	1 (0.1%)	0
TEMAZEPAM	1 (0.1%)	0
DIPHENYLMETHANE DERIVATIVES	0	1 (0.1%)
HYDROXYZINE	0	1 (0.1%)
OTHER ANXIOLYTICS	0	1 (0.1%)
DULOXETINE HYDROCHLORIDE	0	1 (0.1%)
ANESTHETICS	2 (0.2%)	0
OPIOID ANESTHETICS	2 (0.2%)	0
FENTANYL	2 (0.2%)	0
OTHER GENERAL ANESTHETICS	1 (0.1%)	0
PROPOFOL	1 (0.1%)	0
ANTIEMETIC PREPARATIONS	1 (0.1%)	1 (0.1%)
IRON BIVALENT, ORAL PREPARATIONS	1 (0.1%)	1 (0.1%)
IRON	1 (0.1%)	1 (0.1%)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	1 (0.1%)	0
CYANOCOBALAMIN	1 (0.1%)	0

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Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CARDIAC THERAPY	1 (0.1%)	1 (0.1%)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (0.1%)	0
PHENYLEPHRINE	1 (0.1%)	0
ANTIARRHYTHMICS, CLASS III	1 (0.1%)	0
AMIODARONE	1 (0.1%)	0
DIGITALIS GLYCOSIDES	0	1 (0.1%)
DIGOXIN	0	1 (0.1%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	2 (0.2%)	0
PROPULSIVES	2 (0.2%)	0
CINITAPRIDE	1 (0.1%)	0
METOCLOPRAMIDE	1 (0.1%)	0
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	0	1 (0.1%)
ACE INHIBITORS, PLAIN	0	1 (0.1%)
LISINAPRIL	0	1 (0.1%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (0.1%)	0
OTHER NON-THERAPEUTIC AUXILIARY PRODUCTS	1 (0.1%)	0
POLYETHYLENE	1 (0.1%)	0
ANTIDIARRHEALS, INTESTINAL	0	1 (0.1%)
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
ANTIDIARRHEAL MICROORGANISMS	0	1 (0.1%)
SACCHAROMYCES BOULARDII	0	1 (0.1%)

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Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIPROPULSIVES	0	1 (0.1%)
LOPERAMIDE	0	1 (0.1%)
ANTIPILEPTICS	0	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	0	1 (0.1%)
LORAZEPAM	0	1 (0.1%)
ANTIGOUT PREPARATIONS	0	1 (0.1%)
PREPARATIONS INCREASING URIC ACID EXCRETION	0	1 (0.1%)
PROBENECID	0	1 (0.1%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	1 (0.1%)	0
ANTIHISTAMINES FOR TOPICAL USE	1 (0.1%)	0
DIPHENHYDRAMINE	1 (0.1%)	0
BETA BLOCKING AGENTS	0	1 (0.1%)
ALPHA AND BETA BLOCKING AGENTS	0	1 (0.1%)
CARVEDILOL	0	1 (0.1%)
CALCIUM CHANNEL BLOCKERS	1 (0.1%)	0
DIHYDROPYRIDINE DERIVATIVES	1 (0.1%)	0
AMLODIPINE	1 (0.1%)	0
DRUGS FOR CONSTIPATION	0	1 (0.1%)
SOFTENERS, EMOLLIENTS	0	1 (0.1%)
DOCUSATE SODIUM	0	1 (0.1%)

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Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
IMMUNOSUPPRESSANTS	1 (0.1%)	0
SELECTIVE IMMUNOSUPPRESSANTS	1 (0.1%)	0
BARICITINIB	1 (0.1%)	0
LIPID MODIFYING AGENTS	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS	0	1 (0.1%)
ATORVASTATIN	0	1 (0.1%)
NASAL PREPARATIONS	0	1 (0.1%)
SYMPATHOMIMETICS, PLAIN	0	1 (0.1%)
OXYMETAZOLINE	0	1 (0.1%)
OPHTHALMOLOGICALS	0	1 (0.1%)
OTHER OPHTHALMOLOGICALS	0	1 (0.1%)
ARTIFICIAL TEARS [UMBRELLA TERM]	0	1 (0.1%)
PANCREATIC HORMONES	1 (0.1%)	0
GLYCOGENOLYTIC HORMONES	1 (0.1%)	0
GLUCAGON	1 (0.1%)	0
THROAT PREPARATIONS	0	1 (0.1%)
ANTISEPTICS	0	1 (0.1%)
PHENOL	0	1 (0.1%)
THYROID THERAPY	1 (0.1%)	0
THYROID HORMONES	1 (0.1%)	0
LEVOTHYROXINE SODIUM	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.2. Concomitant medications day 1 to day 29
Indication Reason: Treatment of Adverse Event
Modified Full Analysis Set

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant medication	729 (61.1%)	753 (63.2%)
ANALGESICS	264 (22.1%)	276 (23.2%)
ANILIDES	239 (20.0%)	243 (20.4%)
PARACETAMOL	221 (18.5%)	232 (19.5%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL	11 (0.9%)	4 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE HYDROCHLORIDE	8 (0.7%)	4 (0.3%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	4 (0.3%)	3 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYL EPHRINE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL;SALICYLAMIDE	0	1 (0.1%)
BUTALBITAL;CAFFEINE;PARACETAMOL	1 (0.1%)	0
CAFFEINE;PARACETAMOL	1 (0.1%)	0
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;P HENYLEPHRINE	1 (0.1%)	0
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRIN E	1 (0.1%)	0
DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0
IBUPROFEN;PARACETAMOL	0	1 (0.1%)
PARACETAMOL;PHENYLEPHRINE	0	1 (0.1%)
PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
OTHER ANALGESICS AND ANTIPYRETICS	16 (1.3%)	18 (1.5%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
GABAPENTIN	12 (1.0%)	13 (1.1%)
PREGABALIN	2 (0.2%)	2 (0.2%)
DULOXETINE	1 (0.1%)	2 (0.2%)
AMITRIPTYLINE	0	1 (0.1%)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.1%)	0
OTHER ANTIMIGRAINE PREPARATIONS	1 (0.1%)	12 (1.0%)
METOPROLOL	0	4 (0.3%)
AMITRIPTYLINE	1 (0.1%)	2 (0.2%)
TOPIRAMATE	0	3 (0.3%)
BOTULINUM TOXIN TYPE A	0	2 (0.2%)
VERAPAMIL	0	1 (0.1%)
SELECTIVE SEROTONIN (5HT1) AGONISTS	8 (0.7%)	4 (0.3%)
SUMATRIPTAN	4 (0.3%)	4 (0.3%)
RIZATRIPTAN	2 (0.2%)	0
SUMATRIPTAN SUCCINATE	2 (0.2%)	0
SALICYLIC ACID AND DERIVATIVES	5 (0.4%)	3 (0.3%)
ACETYLSALICYLIC ACID	5 (0.4%)	2 (0.2%)
ACETYLSALICYLIC ACID;CAFFEINE	0	1 (0.1%)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	3 (0.3%)	3 (0.3%)
HYDROCODONE BITARTRATE;PARACETAMOL	2 (0.2%)	1 (0.1%)
HYDROCODONE;PARACETAMOL	1 (0.1%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CODEINE;PARACETAMOL	0	1 (0.1%)
OTHER OPIOIDS	0	5 (0.4%)
TRAMADOL	0	5 (0.4%)
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS	0	3 (0.3%)
ERENUMAB	0	1 (0.1%)
FREMANEZUMAB	0	1 (0.1%)
GALCANEZUMAB	0	1 (0.1%)
NATURAL OPIUM ALKALOIDS	1 (0.1%)	2 (0.2%)
OXYCODONE	1 (0.1%)	1 (0.1%)
MORPHINE	0	1 (0.1%)
PYRAZOLONES	0	1 (0.1%)
METAMIZOLE	0	1 (0.1%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	229 (19.2%)	244 (20.5%)
ACE INHIBITORS, PLAIN	118 (9.9%)	131 (11.0%)
LISINAPRIL	99 (8.3%)	98 (8.2%)
ENALAPRIL	11 (0.9%)	16 (1.3%)
BENAZEPRIL	2 (0.2%)	7 (0.6%)
CAPTOPRIL	0	7 (0.6%)
RAMIPRIL	3 (0.3%)	4 (0.3%)
BENAZEPRIL HYDROCHLORIDE	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ENALAPRIL MALEATE	1 (0.1%)	0
FOSINOPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	102 (8.5%)	99 (8.3%)
LOSARTAN	78 (6.5%)	60 (5.0%)
VALSARTAN	8 (0.7%)	11 (0.9%)
OLMESARTAN	5 (0.4%)	6 (0.5%)
TELMISARTAN	4 (0.3%)	6 (0.5%)
OLMESARTAN MEDOXOMIL	3 (0.3%)	5 (0.4%)
IRBESARTAN	2 (0.2%)	4 (0.3%)
LOSARTAN POTASSIUM	3 (0.3%)	3 (0.3%)
CANDESARTAN	0	3 (0.3%)
AZILSARTAN KAMEDOXOMIL	0	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	2 (0.2%)	6 (0.5%)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	2 (0.2%)	1 (0.1%)
HYDROCHLOROTHIAZIDE;LOSARTAN	0	2 (0.2%)
HYDROCHLOROTHIAZIDE;IRBESARTAN	0	1 (0.1%)
HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	1 (0.1%)
HYDROCHLOROTHIAZIDE;VALSARTAN	0	1 (0.1%)
ACE INHIBITORS AND DIURETICS	2 (0.2%)	5 (0.4%)
HYDROCHLOROTHIAZIDE;LISINOPRIL	2 (0.2%)	5 (0.4%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	3 (0.3%)	1 (0.1%)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	2 (0.2%)	1 (0.1%)
AMLODIPINE;BENAZEPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS	2 (0.2%)	1 (0.1%)
SACUBITRIL VALSARTAN SODIUM HYDRATE	2 (0.2%)	1 (0.1%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	0	1 (0.1%)
AMLODIPINE BESILATE;VALSARTAN	0	1 (0.1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	136 (11.4%)	126 (10.6%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	103 (8.6%)	97 (8.1%)
SALBUTAMOL	89 (7.5%)	82 (6.9%)
SALBUTAMOL SULFATE	10 (0.8%)	10 (0.8%)
LEVOSALBUTAMOL	1 (0.1%)	2 (0.2%)
PROCATEROL HYDROCHLORIDE	2 (0.2%)	1 (0.1%)
FORMOTEROL	1 (0.1%)	1 (0.1%)
LEVOSALBUTAMOL HYDROCHLORIDE	1 (0.1%)	0
LEVOSALBUTAMOL TARTRATE	0	1 (0.1%)
SALMETEROL	0	1 (0.1%)
TERBUTALINE	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	25 (2.1%)	19 (1.6%)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	9 (0.8%)	8 (0.7%)
BUDESONIDE;FORMOTEROL FUMARATE	8 (0.7%)	6 (0.5%)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	7 (0.6%)	3 (0.3%)
FLUTICASONE FUROATE;VILANTEROL	1 (0.1%)	0
FLUTICASONE PROPIONATE;SALMETEROL	0	1 (0.1%)
FORMOTEROL FUMARATE;MOMETASONE FUROATE	0	1 (0.1%)
LEUKOTRIENE RECEPTOR ANTAGONISTS	19 (1.6%)	23 (1.9%)
MONTELUKAST	12 (1.0%)	13 (1.1%)
MONTELUKAST SODIUM	7 (0.6%)	10 (0.8%)
GLUCOCORTICIODS	14 (1.2%)	14 (1.2%)
FLUTICASONE PROPIONATE	4 (0.3%)	5 (0.4%)
BECLOMETASONE DIPROPIONATE	2 (0.2%)	4 (0.3%)
BUDESONIDE	3 (0.3%)	3 (0.3%)
FLUTICASONE	5 (0.4%)	0
BECLOMETASONE	0	1 (0.1%)
CICLESONIDE	0	1 (0.1%)
MOMETASONE FUROATE	1 (0.1%)	0
ANTICHOLINERGICS	7 (0.6%)	7 (0.6%)
IPRATROPIUM BROMIDE	4 (0.3%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
IPRATROPIUM	1 (0.1%)	3 (0.3%)
TIOTROPIUM BROMIDE MONOHYDRATE	1 (0.1%)	2 (0.2%)
GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
UMECLIDINIUM BROMIDE	1 (0.1%)	0
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	6 (0.5%)	3 (0.3%)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	2 (0.2%)	1 (0.1%)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	2 (0.2%)	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	1 (0.1%)	0
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	1 (0.1%)	0
UMECLIDINIUM;VILANTEROL	0	1 (0.1%)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0	1 (0.1%)
OMALIZUMAB	0	1 (0.1%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	119 (10.0%)	112 (9.4%)
PROPIONIC ACID DERIVATIVES	105 (8.8%)	93 (7.8%)
IBUPROFEN	92 (7.7%)	80 (6.7%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
NAPROXEN	6 (0.5%)	8 (0.7%)
NAPROXEN SODIUM	8 (0.7%)	4 (0.3%)
HYDROCODONE BITARTRATE;IBUPROFEN	0	1 (0.1%)
OXICAMS	9 (0.8%)	6 (0.5%)
MELOXICAM	9 (0.8%)	6 (0.5%)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	5 (0.4%)	6 (0.5%)
DICLOFENAC	2 (0.2%)	2 (0.2%)
DICLOFENAC POTASSIUM	2 (0.2%)	0
DICLOFENAC SODIUM	1 (0.1%)	1 (0.1%)
ETODOLAC	0	2 (0.2%)
INDOMETACIN	1 (0.1%)	0
KETOROLAC	0	1 (0.1%)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	1 (0.1%)	6 (0.5%)
BENZYDAMINE	1 (0.1%)	1 (0.1%)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	0	2 (0.2%)
BENZYDAMINE HYDROCHLORIDE	0	1 (0.1%)
GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	0	1 (0.1%)
SULFASALAZINE	0	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
COXIBS	2 (0.2%)	1 (0.1%)
CELECOXIB	2 (0.2%)	1 (0.1%)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	0	1 (0.1%)
CURCUMA LONGA	0	1 (0.1%)
OTHER ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH OTHER DRUGS	1 (0.1%)	0
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
LIPID MODIFYING AGENTS	93 (7.8%)	124 (10.4%)
HMG COA REDUCTASE INHIBITORS	87 (7.3%)	118 (9.9%)
ATORVASTATIN	29 (2.4%)	55 (4.6%)
SIMVASTATIN	18 (1.5%)	19 (1.6%)
ROSUVASTATIN	13 (1.1%)	19 (1.6%)
ROSUVASTATIN CALCIUM	6 (0.5%)	14 (1.2%)
ATORVASTATIN CALCIUM	9 (0.8%)	5 (0.4%)
PRAVASTATIN	5 (0.4%)	5 (0.4%)
LOVASTATIN	4 (0.3%)	2 (0.2%)
PRAVASTATIN SODIUM	1 (0.1%)	2 (0.2%)
PITAVASTATIN CALCIUM	2 (0.2%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER LIPID MODIFYING AGENTS	4 (0.3%)	12 (1.0%)
EZETIMIBE	2 (0.2%)	6 (0.5%)
EICOSAPENTAENOIC ACID ETHYL ESTER	0	3 (0.3%)
FISH OIL	2 (0.2%)	1 (0.1%)
OMEGA-3-ACID ETHYL ESTER	0	1 (0.1%)
SITOSTEROL	0	1 (0.1%)
FIBRATES	4 (0.3%)	7 (0.6%)
FENOFIBRATE	4 (0.3%)	4 (0.3%)
GEMFIBROZIL	0	2 (0.2%)
CHOLINE FENOFIBRATE	0	1 (0.1%)
COMBINATIONS OF VARIOUS LIPID MODIFYING AGENTS	2 (0.2%)	0
EZETIMIBE;SIMVASTATIN	2 (0.2%)	0
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	1 (0.1%)	0
CARTHAMUS TINCTORIUS OIL	1 (0.1%)	0
DRUGS USED IN DIABETES	89 (7.5%)	85 (7.1%)
BIGUANIDES	67 (5.6%)	65 (5.5%)
METFORMIN	63 (5.3%)	65 (5.5%)
METFORMIN HYDROCHLORIDE	4 (0.3%)	0
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	17 (1.4%)	8 (0.7%)
INSULIN LISPRO	9 (0.8%)	4 (0.3%)
INSULIN ASPART	6 (0.5%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
INSULIN	1 (0.1%)	2 (0.2%)
INSULIN HUMAN	1 (0.1%)	0
SULFONYLUREAS	11 (0.9%)	13 (1.1%)
GLIPIZIDE	8 (0.7%)	9 (0.8%)
GLIMEPIRIDE	2 (0.2%)	2 (0.2%)
GLIBENCLAMIDE	1 (0.1%)	2 (0.2%)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	12 (1.0%)	10 (0.8%)
INSULIN GLARGINE	6 (0.5%)	9 (0.8%)
INSULIN DETEMIR	4 (0.3%)	0
INSULIN DEGLUDEC	2 (0.2%)	1 (0.1%)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	6 (0.5%)	9 (0.8%)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	2 (0.2%)	5 (0.4%)
EMPAGLIFLOZIN	4 (0.3%)	2 (0.2%)
CANAGLIFLOZIN	0	2 (0.2%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	7 (0.6%)	6 (0.5%)
SITAGLIPTIN PHOSPHATE	6 (0.5%)	5 (0.4%)
GEMIGLIPTIN	0	1 (0.1%)
LINAGLIPTIN	1 (0.1%)	0
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES	9 (0.8%)	3 (0.3%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DULAGLUTIDE	4 (0.3%)	1 (0.1%)
SEMAGLUTIDE	3 (0.3%)	2 (0.2%)
EXENATIDE	1 (0.1%)	0
LIRAGLUTIDE	1 (0.1%)	0
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	2 (0.2%)	4 (0.3%)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	2 (0.2%)	1 (0.1%)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	0	2 (0.2%)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	0	1 (0.1%)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	3 (0.3%)	1 (0.1%)
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	2 (0.2%)	1 (0.1%)
INSULIN HUMAN INJECTION, ISOPHANE	1 (0.1%)	0
THIAZOLIDINEDIONES	1 (0.1%)	1 (0.1%)
PIOGLITAZONE	0	1 (0.1%)
PIOGLITAZONE HYDROCHLORIDE	1 (0.1%)	0
ALPHA GLUCOSIDASE INHIBITORS	1 (0.1%)	0
ACARBOSE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	0	1 (0.1%)
INSULIN ASPART;INSULIN ASPART PROTAMINE	0	1 (0.1%)
BETA BLOCKING AGENTS	68 (5.7%)	68 (5.7%)
BETA BLOCKING AGENTS, SELECTIVE	50 (4.2%)	57 (4.8%)
METOPROLOL	28 (2.3%)	28 (2.3%)
ATENOLOL	16 (1.3%)	15 (1.3%)
NEBIVOLOL HYDROCHLORIDE	1 (0.1%)	6 (0.5%)
METOPROLOL TARTRATE	3 (0.3%)	3 (0.3%)
METOPROLOL SUCCINATE	1 (0.1%)	4 (0.3%)
BISOPROLOL	1 (0.1%)	1 (0.1%)
ALPHA AND BETA BLOCKING AGENTS	15 (1.3%)	8 (0.7%)
CARVEDILOL	13 (1.1%)	8 (0.7%)
LABETALOL	2 (0.2%)	0
LABETALOL HYDROCHLORIDE	1 (0.1%)	0
BETA BLOCKING AGENTS, NON-SELECTIVE	2 (0.2%)	4 (0.3%)
PROPRANOLOL	2 (0.2%)	2 (0.2%)
SOTALOL	0	2 (0.2%)
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	1 (0.1%)	0
BISOPROLOL;HYDROCHLOROTHIAZIDE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CALCIUM CHANNEL BLOCKERS	58 (4.9%)	74 (6.2%)
DIHYDROPYRIDINE DERIVATIVES	52 (4.4%)	70 (5.9%)
AMLODIPINE	42 (3.5%)	60 (5.0%)
NIFEDIPINE	5 (0.4%)	5 (0.4%)
AMLODIPINE BESILATE	5 (0.4%)	4 (0.3%)
FELODIPINE	0	1 (0.1%)
BENZOTHAZEPINE DERIVATIVES	4 (0.3%)	3 (0.3%)
DILTIAZEM	4 (0.3%)	2 (0.2%)
DILTIAZEM HYDROCHLORIDE	0	1 (0.1%)
PHENYLALKYLAMINE DERIVATIVES	2 (0.2%)	1 (0.1%)
VERAPAMIL	2 (0.2%)	1 (0.1%)
DIURETICS	68 (5.7%)	61 (5.1%)
THIAZIDES, PLAIN	48 (4.0%)	46 (3.9%)
HYDROCHLOROTHIAZIDE	48 (4.0%)	46 (3.9%)
SULFONAMIDES, PLAIN	12 (1.0%)	11 (0.9%)
FUROSEMIDE	4 (0.3%)	8 (0.7%)
CHLORTALIDONE	5 (0.4%)	2 (0.2%)
BUMETANIDE	1 (0.1%)	1 (0.1%)
INDAPAMIDE	2 (0.2%)	0
TORASEMIDE	1 (0.1%)	0
ALDOSTERONE ANTAGONISTS	3 (0.3%)	5 (0.4%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SPIRONOLACTONE	3 (0.3%)	5 (0.4%)
DIURETICS	2 (0.2%)	1 (0.1%)
ISOSORBIDE	2 (0.2%)	1 (0.1%)
OTHER POTASSIUM-SPARING AGENTS	1 (0.1%)	2 (0.2%)
TRIAMTERENE	1 (0.1%)	2 (0.2%)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	2 (0.2%)	0
HYDROCHLOROTHIAZIDE;TRIAMTERENE	2 (0.2%)	0
ANTIBACTERIALS FOR SYSTEMIC USE	54 (4.5%)	61 (5.1%)
MACROLIDES	34 (2.8%)	46 (3.9%)
AZITHROMYCIN	33 (2.8%)	44 (3.7%)
CLARITHROMYCIN	0	2 (0.2%)
AZITHROMYCIN DIHYDRATE	1 (0.1%)	0
FLUOROQUINOLONES	3 (0.3%)	5 (0.4%)
LEVOFLOXACIN	1 (0.1%)	5 (0.4%)
CIPROFLOXACIN	2 (0.2%)	0
TETRACYCLINES	6 (0.5%)	2 (0.2%)
DOXYCYCLINE	5 (0.4%)	2 (0.2%)
MINOCYCLINE	1 (0.1%)	0
THIRD-GENERATION CEPHALOSPORINS	3 (0.3%)	3 (0.3%)
CEFTRIAZONE	2 (0.2%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CEFDINIR	1 (0.1%)	1 (0.1%)
CEFTRIAZONE SODIUM	0	1 (0.1%)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	3 (0.3%)	2 (0.2%)
AMOXICILLIN;CLAVULANIC ACID	3 (0.3%)	2 (0.2%)
PENICILLINS WITH EXTENDED SPECTRUM	2 (0.2%)	3 (0.3%)
AMOXICILLIN	2 (0.2%)	2 (0.2%)
AMPICILLIN	0	1 (0.1%)
FIRST-GENERATION CEPHALOSPORINS	1 (0.1%)	1 (0.1%)
CEFALEXIN	1 (0.1%)	1 (0.1%)
GLYCOPEPTIDE ANTIBACTERIALS	1 (0.1%)	0
VANCOMYCIN	1 (0.1%)	0
NITROFURAN DERIVATIVES	0	1 (0.1%)
NITROFURANTOIN	0	1 (0.1%)
OTHER ANTIBACTERIALS	1 (0.1%)	0
METHENAMINE	1 (0.1%)	0
TRIMETHOPRIM AND DERIVATIVES	1 (0.1%)	0
TRIMETHOPRIM	1 (0.1%)	0
ANTITHROMBOTIC AGENTS	54 (4.5%)	59 (4.9%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	39 (3.3%)	52 (4.4%)
ACETYLSALICYLIC ACID	39 (3.3%)	47 (3.9%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
CLOPIDOGREL	2 (0.2%)	6 (0.5%)
CLOPIDOGREL BISULFATE	1 (0.1%)	3 (0.3%)
PRASUGREL	0	1 (0.1%)
PRASUGREL HYDROCHLORIDE	0	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	14 (1.2%)	8 (0.7%)
APIXABAN	10 (0.8%)	5 (0.4%)
RIVAROXABAN	4 (0.3%)	3 (0.3%)
HEPARIN GROUP	3 (0.3%)	0
ENOXAPARIN	2 (0.2%)	0
ENOXAPARIN SODIUM	1 (0.1%)	0
VITAMIN K ANTAGONISTS	0	1 (0.1%)
WARFARIN	0	1 (0.1%)
PSYCHOANALEPTICS	49 (4.1%)	63 (5.3%)
OTHER ANTIDEPRESSANTS	20 (1.7%)	28 (2.3%)
TRAZODONE	5 (0.4%)	7 (0.6%)
BUPROPION HYDROCHLORIDE	8 (0.7%)	3 (0.3%)
LAMOTRIGINE	5 (0.4%)	4 (0.3%)
BUPROPION	0	7 (0.6%)
DULOXETINE	2 (0.2%)	2 (0.2%)
DULOXETINE HYDROCHLORIDE	2 (0.2%)	0
VENLAFAXINE	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DESVENLAFAXINE	0	1 (0.1%)
DESVENLAFAXINE SUCCINATE MONOHYDRATE	0	1 (0.1%)
MIRTAZAPINE	0	1 (0.1%)
VENLAFAXINE HYDROCHLORIDE	0	1 (0.1%)
VILAZODONE HYDROCHLORIDE	1 (0.1%)	0
VORTIOXETINE HYDROBROMIDE	0	1 (0.1%)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	20 (1.7%)	21 (1.8%)
CITALOPRAM	5 (0.4%)	6 (0.5%)
SERTRALINE	4 (0.3%)	5 (0.4%)
ESCITALOPRAM OXALATE	5 (0.4%)	2 (0.2%)
CITALOPRAM HYDROBROMIDE	2 (0.2%)	1 (0.1%)
ESCITALOPRAM	1 (0.1%)	2 (0.2%)
FLUOXETINE	3 (0.3%)	0
FLUOXETINE HYDROCHLORIDE	0	2 (0.2%)
SERTRALINE HYDROCHLORIDE	0	2 (0.2%)
PAROXETINE	0	1 (0.1%)
CENTRALLY ACTING SYMPATHOMIMETICS	14 (1.2%)	14 (1.2%)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	9 (0.8%)	10 (0.8%)
LISDEXAMFETAMINE MESILATE	1 (0.1%)	2 (0.2%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
AMFETAMINE;DEXAMFETAMINE	1 (0.1%)	0
LISDEXAMFETAMINE	1 (0.1%)	0
METHYLPHENIDATE	1 (0.1%)	0
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	2 (0.2%)	4 (0.3%)
AMITRIPTYLINE	2 (0.2%)	2 (0.2%)
DOXEPIN	0	1 (0.1%)
NORTRIPTYLINE	0	1 (0.1%)
ANTICHOLINESTERASES	1 (0.1%)	2 (0.2%)
DONEPEZIL	1 (0.1%)	2 (0.2%)
OTHER ANTI-DEMENTIA DRUGS	0	2 (0.2%)
MEMANTINE	0	1 (0.1%)
MEMANTINE HYDROCHLORIDE	0	1 (0.1%)
XANTHINE DERIVATIVES	0	2 (0.2%)
CAFFEINE	0	2 (0.2%)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	1 (0.1%)	0
GUANFACINE	1 (0.1%)	0
DRUGS FOR ACID RELATED DISORDERS	58 (4.9%)	47 (3.9%)
PROTON PUMP INHIBITORS	54 (4.5%)	43 (3.6%)
OMEPRAZOLE	35 (2.9%)	20 (1.7%)
PANTOPRAZOLE	12 (1.0%)	12 (1.0%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ESOMEPRAZOLE	5 (0.4%)	5 (0.4%)
LANSOPRAZOLE	2 (0.2%)	2 (0.2%)
DEXLANSOPRAZOLE	0	2 (0.2%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0	2 (0.2%)
H2-RECEPTOR ANTAGONISTS	4 (0.3%)	2 (0.2%)
FAMOTIDINE	4 (0.3%)	1 (0.1%)
CIMETIDINE	0	1 (0.1%)
ALUMINIUM COMPOUNDS	1 (0.1%)	0
ALUMINIUM HYDROXIDE	1 (0.1%)	0
ANTACIDS WITH SODIUM BICARBONATE	0	1 (0.1%)
SODIUM BICARBONATE	0	1 (0.1%)
CALCIUM COMPOUNDS	1 (0.1%)	0
CALCIUM CARBONATE	1 (0.1%)	0
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	1 (0.1%)	0
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	1 (0.1%)	0
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	0	1 (0.1%)
BISMUTH SUBSALICYLATE	0	1 (0.1%)
PSYCHOLEPTICS	50 (4.2%)	53 (4.4%)
OTHER ANXIOLYTICS	15 (1.3%)	23 (1.9%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ESCITALOPRAM	2 (0.2%)	7 (0.6%)
SERTRALINE	3 (0.3%)	4 (0.3%)
ESCITALOPRAM OXALATE	3 (0.3%)	3 (0.3%)
FLUOXETINE	0	3 (0.3%)
PAROXETINE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
SERTRALINE HYDROCHLORIDE	1 (0.1%)	2 (0.2%)
PAROXETINE	1 (0.1%)	1 (0.1%)
AMITRIPTYLINE	0	1 (0.1%)
DULOXETINE	1 (0.1%)	0
DULOXETINE HYDROCHLORIDE	1 (0.1%)	0
FLUOXETINE HYDROCHLORIDE	1 (0.1%)	0
LAVANDULA ANGUSTIFOLIA ESSENTIAL OIL	1 (0.1%)	0
PROPRANOLOL	0	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	14 (1.2%)	19 (1.6%)
CLONAZEPAM	4 (0.3%)	6 (0.5%)
LORAZEPAM	3 (0.3%)	7 (0.6%)
ALPRAZOLAM	4 (0.3%)	3 (0.3%)
TEMAZEPAM	2 (0.2%)	2 (0.2%)
DIAZEPAM	1 (0.1%)	1 (0.1%)
MELATONIN RECEPTOR AGONISTS	8 (0.7%)	4 (0.3%)
MELATONIN	8 (0.7%)	4 (0.3%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
AZASPIRODECANEDIONE DERIVATIVES	8 (0.7%)	1 (0.1%)
BUSPIRONE	7 (0.6%)	1 (0.1%)
BUSPIRONE HYDROCHLORIDE	1 (0.1%)	0
BENZODIAZEPINE RELATED DRUGS	5 (0.4%)	4 (0.3%)
ZOLPIDEM TARTRATE	3 (0.3%)	2 (0.2%)
ZOLPIDEM	1 (0.1%)	2 (0.2%)
ESZOPICLONE	1 (0.1%)	0
OTHER ANTIPSYCHOTICS	3 (0.3%)	3 (0.3%)
ARIPIRAZOLE	1 (0.1%)	3 (0.3%)
VALPROATE SEMISODIUM	2 (0.2%)	0
RISPERIDONE	1 (0.1%)	0
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	4 (0.3%)	1 (0.1%)
QUETIAPINE	1 (0.1%)	1 (0.1%)
QUETIAPINE FUMARATE	2 (0.2%)	0
OLANZAPINE	1 (0.1%)	0
OTHER HYPNOTICS AND SEDATIVES	2 (0.2%)	3 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	2 (0.2%)
DOXEPIN	1 (0.1%)	1 (0.1%)
SUVOREXANT	1 (0.1%)	0
DIPHENYLMETHANE DERIVATIVES	1 (0.1%)	2 (0.2%)
HYDROXYZINE	1 (0.1%)	1 (0.1%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
HYDROXYZINE EMBONATE	0	1 (0.1%)
BARBITURATES, PLAIN	0	2 (0.2%)
BUTALBITAL	0	2 (0.2%)
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	2 (0.2%)	0
PROCHLORPERAZINE	2 (0.2%)	0
PSYCHOLEPTICS	0	1 (0.1%)
CANNABIDIOL	0	1 (0.1%)
THYROID THERAPY	43 (3.6%)	53 (4.4%)
THYROID HORMONES	43 (3.6%)	49 (4.1%)
LEVOTHYROXINE	26 (2.2%)	30 (2.5%)
LEVOTHYROXINE SODIUM	16 (1.3%)	19 (1.6%)
LEVOTHYROXINE;LIOTHYRONINE	2 (0.2%)	0
LIOTHYRONINE	1 (0.1%)	1 (0.1%)
LIOTHYRONINE SODIUM	1 (0.1%)	0
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0	4 (0.3%)
THIAMAZOLE	0	4 (0.3%)
COUGH AND COLD PREPARATIONS	39 (3.3%)	33 (2.8%)
EXPECTORANTS	17 (1.4%)	14 (1.2%)
GUAIFENESIN	17 (1.4%)	14 (1.2%)
OTHER COUGH SUPPRESSANTS	9 (0.8%)	5 (0.4%)
BENZONATATE	7 (0.6%)	4 (0.3%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DROPROPIZINE	2 (0.2%)	1 (0.1%)
OPIUM ALKALOIDS AND DERIVATIVES	5 (0.4%)	8 (0.7%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (0.1%)	4 (0.3%)
DEXTROMETHORPHAN	2 (0.2%)	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
CHLORPHENAMINE;HYDROCODONE BITARTRATE	0	1 (0.1%)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	0
OPIUM DERIVATIVES AND EXPECTORANTS	4 (0.3%)	7 (0.6%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	1 (0.1%)	2 (0.2%)
CODEINE PHOSPHATE;GUAIFENESIN	1 (0.1%)	2 (0.2%)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	1 (0.1%)	2 (0.2%)
DEXTROMETHORPHAN;GUAIFENESIN	1 (0.1%)	1 (0.1%)
MUCOLYTICS	5 (0.4%)	2 (0.2%)
AMBROXOL	2 (0.2%)	1 (0.1%)
ACETYLCYSTEINE	1 (0.1%)	0
BROMHEXINE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
BROMHEXINE HYDROCHLORIDE	0	1 (0.1%)
ERDOSTEINE	1 (0.1%)	0
COUGH AND COLD PREPARATIONS	3 (0.3%)	1 (0.1%)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL	0	1 (0.1%)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
EUCALYPTUS GLOBULUS OIL;MENTHOL	1 (0.1%)	0
MENTHOL	1 (0.1%)	0
OTHER COUGH SUPPRESSANTS AND EXPECTORANTS	1 (0.1%)	0
AMBROXOL;DROPROPIZINE	1 (0.1%)	0
ANTIHISTAMINES FOR SYSTEMIC USE	26 (2.2%)	33 (2.8%)
PIPERAZINE DERIVATIVES	14 (1.2%)	15 (1.3%)
CETIRIZINE HYDROCHLORIDE	8 (0.7%)	8 (0.7%)
CETIRIZINE	6 (0.5%)	7 (0.6%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	9 (0.8%)	10 (0.8%)
LORATADINE	5 (0.4%)	8 (0.7%)
FEXOFENADINE HYDROCHLORIDE	3 (0.3%)	2 (0.2%)
EPINASTINE	1 (0.1%)	0
AMINOALKYL ETHERS	4 (0.3%)	5 (0.4%)
DIPHENHYDRAMINE HYDROCHLORIDE	3 (0.3%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DOXYLAMINE SUCCINATE	1 (0.1%)	2 (0.2%)
CARBINOXAMINE	0	1 (0.1%)
PHENOTHIAZINE DERIVATIVES	1 (0.1%)	2 (0.2%)
PROMETHAZINE	1 (0.1%)	2 (0.2%)
SUBSTITUTED ALKYLAMINES	0	1 (0.1%)
DEXBROMPHENIRAMINE	0	1 (0.1%)
VITAMINS	26 (2.2%)	26 (2.2%)
ASCORBIC ACID (VITAMIN C), PLAIN	17 (1.4%)	20 (1.7%)
ASCORBIC ACID	17 (1.4%)	20 (1.7%)
VITAMIN D AND ANALOGUES	19 (1.6%)	15 (1.3%)
VITAMIN D NOS	14 (1.2%)	10 (0.8%)
COLECALCIFEROL	4 (0.3%)	5 (0.4%)
ERGOCALCIFEROL	1 (0.1%)	0
MULTIVITAMINS, PLAIN	0	1 (0.1%)
VITAMINS NOS	0	1 (0.1%)
OTHER PLAIN VITAMIN PREPARATIONS	1 (0.1%)	0
VITAMIN B NOS	1 (0.1%)	0
VITAMINS WITH MINERALS	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID;	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	24 (2.0%)	16 (1.3%)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	9 (0.8%)	9 (0.8%)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFIVIR ALAFENAMIDE FUMARATE	4 (0.3%)	6 (0.5%)
EMTRICITABINE;TENOFIVIR ALAFENAMIDE FUMARATE	1 (0.1%)	1 (0.1%)
EMTRICITABINE;TENOFIVIR DISOPROXIL FUMARATE	1 (0.1%)	1 (0.1%)
ABACAVIR SULFATE;LAMIVUDINE	1 (0.1%)	0
BICTEGRAVIR;EMTRICITABINE;TENOFIVIR	1 (0.1%)	0
DOLUTEGRAVIR;LAMIVUDINE	0	1 (0.1%)
EFAVIRENZ;EMTRICITABINE;TENOFIVIR DISOPROXIL FUMARATE	1 (0.1%)	0
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	12 (1.0%)	6 (0.5%)
VALACICLOVIR HYDROCHLORIDE	5 (0.4%)	2 (0.2%)
VALACICLOVIR	3 (0.3%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
REMDESIVIR	3 (0.3%)	0
ACICLOVIR	0	1 (0.1%)
RIBAVIRIN	0	1 (0.1%)
VALGANCICLOVIR HYDROCHLORIDE	1 (0.1%)	0
NEURAMINIDASE INHIBITORS	1 (0.1%)	1 (0.1%)
OSELTAMIVIR	1 (0.1%)	1 (0.1%)
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	0
AMANTADINE	1 (0.1%)	0
INTEGRASE INHIBITORS	1 (0.1%)	0
DOLUTEGRAVIR SODIUM	1 (0.1%)	0
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1%)	0
EFAVIRENZ	1 (0.1%)	0
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
ABACAVIR	0	1 (0.1%)
OTHER ANTIVIRALS	1 (0.1%)	0
BAMLANIVIMAB	1 (0.1%)	0
NASAL PREPARATIONS	16 (1.3%)	18 (1.5%)
CORTICOSTEROIDS	8 (0.7%)	13 (1.1%)
FLUTICASONE PROPIONATE	4 (0.3%)	7 (0.6%)
FLUTICASONE	4 (0.3%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
BUDESONIDE	0	2 (0.2%)
AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE	0	1 (0.1%)
TRIAMCINOLONE ACETONIDE	0	1 (0.1%)
SYMPATHOMIMETICS	4 (0.3%)	3 (0.3%)
PSEUDOEPHEDRINE	0	2 (0.2%)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (0.2%)	0
BROMPHENIRAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.1%)	0
PHENYLEPHRINE	1 (0.1%)	0
PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.1%)
SYMPATHOMIMETICS, PLAIN	3 (0.3%)	1 (0.1%)
OXYMETAZOLINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
TETRYZOLINE	1 (0.1%)	0
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	1 (0.1%)	1 (0.1%)
AZELASTINE	1 (0.1%)	1 (0.1%)
OTHER NASAL PREPARATIONS	1 (0.1%)	1 (0.1%)
IPRATROPIUM BROMIDE	0	1 (0.1%)
OTHER NASAL PREPARATIONS	1 (0.1%)	0
UROLOGICALS	17 (1.4%)	11 (0.9%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ALPHA-ADRENORECEPTOR ANTAGONISTS	11 (0.9%)	9 (0.8%)
TAMSULOSIN	9 (0.8%)	4 (0.3%)
TAMSULOSIN HYDROCHLORIDE	1 (0.1%)	4 (0.3%)
ALFUZOSIN	0	1 (0.1%)
TERAZOSIN	1 (0.1%)	0
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	2 (0.2%)	2 (0.2%)
FINASTERIDE	2 (0.2%)	2 (0.2%)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	3 (0.3%)	0
DULOXETINE HYDROCHLORIDE	1 (0.1%)	0
OXYBUTYNIN	1 (0.1%)	0
OXYBUTYNIN HYDROCHLORIDE	1 (0.1%)	0
DRUGS USED IN ERECTILE DYSFUNCTION	3 (0.3%)	0
SILDENAFIL	2 (0.2%)	0
TADALAFIL	1 (0.1%)	0
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	0	1 (0.1%)
TADALAFIL	0	1 (0.1%)
URINARY CONCREMENT SOLVENTS	1 (0.1%)	0
SODIUM BICARBONATE	1 (0.1%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	15 (1.3%)	9 (0.8%)
GLUCOCORTICOIDS	15 (1.3%)	9 (0.8%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DEXAMETHASONE	6 (0.5%)	2 (0.2%)
PREDNISONE	4 (0.3%)	3 (0.3%)
METHYLPREDNISOLONE	4 (0.3%)	2 (0.2%)
CORTISONE	1 (0.1%)	0
METHYLPREDNISOLONE ACETATE	0	1 (0.1%)
TRIAMCINOLONE ACETONIDE	0	1 (0.1%)
MINERAL SUPPLEMENTS	10 (0.8%)	13 (1.1%)
ZINC	9 (0.8%)	10 (0.8%)
ZINC	8 (0.7%)	10 (0.8%)
ZINC ACETATE;ZINC GLUCONATE	1 (0.1%)	0
MAGNESIUM	1 (0.1%)	2 (0.2%)
MAGNESIUM	1 (0.1%)	2 (0.2%)
POTASSIUM	1 (0.1%)	2 (0.2%)
POTASSIUM CHLORIDE	0	2 (0.2%)
POTASSIUM	1 (0.1%)	0
CALCIUM	0	2 (0.2%)
CALCIUM	0	1 (0.1%)
CALCIUM CHLORIDE	0	1 (0.1%)
SODIUM	1 (0.1%)	0
SODIUM	1 (0.1%)	0
IMMUNOSUPPRESSANTS	8 (0.7%)	14 (1.2%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER IMMUNOSUPPRESSANTS	6 (0.5%)	7 (0.6%)
HYDROXYCHLOROQUINE	4 (0.3%)	4 (0.3%)
METHOTREXATE	2 (0.2%)	3 (0.3%)
AZATHIOPRINE	0	1 (0.1%)
SELECTIVE IMMUNOSUPPRESSANTS	2 (0.2%)	3 (0.3%)
APREMILAST	1 (0.1%)	0
BELIMUMAB	0	1 (0.1%)
MYCOPHENOLATE MOFETIL	1 (0.1%)	0
SIROLIMUS	0	1 (0.1%)
UPADACITINIB	0	1 (0.1%)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	0	3 (0.3%)
ADALIMUMAB	0	2 (0.2%)
ETANERCEPT	0	1 (0.1%)
CALCINEURIN INHIBITORS	1 (0.1%)	0
TACROLIMUS	1 (0.1%)	0
INTERLEUKIN INHIBITORS	0	1 (0.1%)
BRODALUMAB	0	1 (0.1%)
ANTIGOUT PREPARATIONS	9 (0.8%)	11 (0.9%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	6 (0.5%)	9 (0.8%)
ALLOPURINOL	6 (0.5%)	9 (0.8%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	3 (0.3%)	3 (0.3%)
COLCHICINE	3 (0.3%)	3 (0.3%)
MUSCLE RELAXANTS	8 (0.7%)	12 (1.0%)
OTHER CENTRALLY ACTING AGENTS	8 (0.7%)	9 (0.8%)
CYCLOBENZAPRINE	3 (0.3%)	4 (0.3%)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (0.1%)	4 (0.3%)
TIZANIDINE	3 (0.3%)	0
TIZANIDINE HYDROCHLORIDE	1 (0.1%)	1 (0.1%)
CARBAMIC ACID ESTERS	0	3 (0.3%)
METHOCARBAMOL	0	3 (0.3%)
CARDIAC THERAPY	11 (0.9%)	7 (0.6%)
ORGANIC NITRATES	3 (0.3%)	3 (0.3%)
GLYCERYL TRINITRATE	2 (0.2%)	2 (0.2%)
ISOSORBIDE DINITRATE	1 (0.1%)	0
ISOSORBIDE MONONITRATE	0	1 (0.1%)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (0.1%)	3 (0.3%)
EPINEPHRINE	0	3 (0.3%)
PHENYLEPHRINE	1 (0.1%)	0
ANTIARRHYTHMICS, CLASS III	4 (0.3%)	0
AMIODARONE	2 (0.2%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DOFETILIDE	2 (0.2%)	0
DIGITALIS GLYCOSIDES	2 (0.2%)	0
DIGOXIN	2 (0.2%)	0
OTHER CARDIAC PREPARATIONS	0	1 (0.1%)
IVABRADINE HYDROCHLORIDE	0	1 (0.1%)
OTHER VASODILATORS USED IN CARDIAC DISEASES	1 (0.1%)	0
SACUBITRIL	1 (0.1%)	0
ANTIEPILEPTICS	8 (0.7%)	8 (0.7%)
OTHER ANTIEPILEPTICS	4 (0.3%)	3 (0.3%)
LEVETIRACETAM	3 (0.3%)	1 (0.1%)
GABAPENTIN	0	1 (0.1%)
LACOSAMIDE	0	1 (0.1%)
TOPIRAMATE	1 (0.1%)	0
CARBOXAMIDE DERIVATIVES	2 (0.2%)	1 (0.1%)
OXCARBAZEPINE	2 (0.2%)	1 (0.1%)
FATTY ACID DERIVATIVES	1 (0.1%)	2 (0.2%)
TIAGABINE	0	1 (0.1%)
VALPROATE SEMISODIUM	1 (0.1%)	0
VALPROATE SODIUM	0	1 (0.1%)
BENZODIAZEPINE DERIVATIVES	2 (0.2%)	0
CLOBAZAM	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DIAZEPAM	1 (0.1%)	0
HYDANTOIN DERIVATIVES	0	2 (0.2%)
PHENYTOIN	0	1 (0.1%)
PHENYTOIN SODIUM	0	1 (0.1%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	10 (0.8%)	5 (0.4%)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	5 (0.4%)	2 (0.2%)
ESTRADIOL	5 (0.4%)	2 (0.2%)
-OXOANDROSTEN (4) DERIVATIVES	3 (0.3%)	3 (0.3%)
TESTOSTERONE	1 (0.1%)	2 (0.2%)
TESTOSTERONE CIPIONATE	2 (0.2%)	1 (0.1%)
PREGNEN (4) DERIVATIVES	2 (0.2%)	0
PROGESTERONE	2 (0.2%)	0
PROGESTOGENS	0	2 (0.2%)
DROSPIRENONE	0	1 (0.1%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.1%)
ESTROGENS, COMBINATIONS WITH OTHER DRUGS	1 (0.1%)	0
BAZEDOXIFENE;ESTROGENS CONJUGATED	1 (0.1%)	0
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	1 (0.1%)	0
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIHYPERTENSIVES	6 (0.5%)	4 (0.3%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	2 (0.2%)	2 (0.2%)
DOXAZOSIN	0	2 (0.2%)
DOXAZOSIN MESILATE	1 (0.1%)	0
PRAZOSIN	1 (0.1%)	0
HYDRAZINOPHTHALAZINE DERIVATIVES	3 (0.3%)	1 (0.1%)
HYDRALAZINE	3 (0.3%)	1 (0.1%)
IMIDAZOLINE RECEPTOR AGONISTS	2 (0.2%)	1 (0.1%)
CLONIDINE	1 (0.1%)	1 (0.1%)
GUANFACINE HYDROCHLORIDE	1 (0.1%)	0
OPHTHALMOLOGICALS	9 (0.8%)	1 (0.1%)
OTHER OPHTHALMOLOGICALS	3 (0.3%)	1 (0.1%)
LIFITEGRAST	2 (0.2%)	0
ASCORBIC ACID;TOCOPHERYL ACETATE;XANTOXYL;ZEAXANTHIN;ZINC	1 (0.1%)	0
HYPROMELLOSE	0	1 (0.1%)
PROSTAGLANDIN ANALOGUES	4 (0.3%)	0
LATANOPROST	4 (0.3%)	0
BETA BLOCKING AGENTS	2 (0.2%)	0
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	1 (0.1%)	0
TIMOLOL	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIBIOTICS	1 (0.1%)	0
ERYTHROMYCIN	1 (0.1%)	0
ANTI-PARKINSON DRUGS	5 (0.4%)	4 (0.3%)
DOPAMINE AGONISTS	4 (0.3%)	2 (0.2%)
PRAMIPEXOLE	2 (0.2%)	0
ROPINIROLE	1 (0.1%)	1 (0.1%)
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	0	1 (0.1%)
ROPINIROLE HYDROCHLORIDE	1 (0.1%)	0
DOPA AND DOPA DERIVATIVES	2 (0.2%)	2 (0.2%)
CARBIDOPA	2 (0.2%)	1 (0.1%)
CARBIDOPA;LEVODOPA	0	1 (0.1%)
LEVODOPA	1 (0.1%)	0
ALL OTHER THERAPEUTIC PRODUCTS	6 (0.5%)	2 (0.2%)
MEDICAL GASES	5 (0.4%)	1 (0.1%)
OXYGEN	5 (0.4%)	1 (0.1%)
OTHER THERAPEUTIC PRODUCTS	1 (0.1%)	1 (0.1%)
DIPENTEN	1 (0.1%)	0
HOMEOPATHICS NOS	0	1 (0.1%)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA	1 (0.1%)	0
SODIUM ZIRCONIUM CYCLOSILICATE	1 (0.1%)	0

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIEMETICS AND ANTINAUSEANTS	5 (0.4%)	2 (0.2%)
OTHER ANTIEMETICS	3 (0.3%)	1 (0.1%)
PROMETHAZINE	2 (0.2%)	0
DIFENIDOL	0	1 (0.1%)
MECLOZINE	1 (0.1%)	0
PROMETHAZINE HYDROCHLORIDE	1 (0.1%)	0
SEROTONIN (5HT3) ANTAGONISTS	3 (0.3%)	1 (0.1%)
ONDANSETRON	3 (0.3%)	1 (0.1%)
ANTHELMINTICS	5 (0.4%)	1 (0.1%)
AVERMECTINES	5 (0.4%)	1 (0.1%)
IVERMECTIN	5 (0.4%)	1 (0.1%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	3 (0.3%)	3 (0.3%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0.1%)	3 (0.3%)
TRIAMCINOLONE ACETONIDE	0	2 (0.2%)
DESONIDE	1 (0.1%)	0
TRIAMCINOLONE	0	1 (0.1%)
CORTICOSTEROIDS, POTENT (GROUP III)	1 (0.1%)	0
ULOBETASOL	1 (0.1%)	0
CORTICOSTEROIDS, WEAK (GROUP I)	1 (0.1%)	0
HYDROCORTISONE	1 (0.1%)	0
OTHER NERVOUS SYSTEM DRUGS	2 (0.2%)	4 (0.3%)

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Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER NERVOUS SYSTEM DRUGS	0	4 (0.3%)
GABAPENTIN	0	3 (0.3%)
EDARAVONE	0	1 (0.1%)
RILUZOLE	0	1 (0.1%)
ANTIVERTIGO PREPARATIONS	2 (0.2%)	0
MECLOZINE	1 (0.1%)	0
MECLOZINE HYDROCHLORIDE	1 (0.1%)	0
ANTIANEMIC PREPARATIONS	4 (0.3%)	1 (0.1%)
IRON BIVALENT, ORAL PREPARATIONS	3 (0.3%)	1 (0.1%)
FERROUS SULFATE	2 (0.2%)	1 (0.1%)
IRON	1 (0.1%)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	1 (0.1%)	0
VITAMIN B12 NOS	1 (0.1%)	0
ANTINEOPLASTIC AGENTS	3 (0.3%)	2 (0.2%)
MONOCLONAL ANTIBODIES	2 (0.2%)	1 (0.1%)
RITUXIMAB	2 (0.2%)	0
BEVACIZUMAB	0	1 (0.1%)
BRUTON'S TYROSINE KINASE (BTK) INHIBITORS	0	1 (0.1%)
IBRUTINIB	0	1 (0.1%)
CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS	1 (0.1%)	0
PALBOCICLIB	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DRUGS FOR TREATMENT OF BONE DISEASES	1 (0.1%)	3 (0.3%)
BISPHOSPHONATES	1 (0.1%)	1 (0.1%)
ALENDRONATE SODIUM	1 (0.1%)	1 (0.1%)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	0	2 (0.2%)
DENOSUMAB	0	2 (0.2%)
ANTI-ACNE PREPARATIONS	1 (0.1%)	2 (0.2%)
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE	0	1 (0.1%)
DAPSONE	0	1 (0.1%)
RETINOIDS FOR TOPICAL USE IN ACNE	1 (0.1%)	0
TRETINOIN	1 (0.1%)	0
RETINOIDS FOR TREATMENT OF ACNE	0	1 (0.1%)
ISOTRETINOIN	0	1 (0.1%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	2 (0.2%)	1 (0.1%)
OTHER CHEMOTHERAPEUTICS	2 (0.2%)	0
METRONIDAZOLE	2 (0.2%)	0
ANTIVIRALS	0	1 (0.1%)
IMIQUIMOD	0	1 (0.1%)
ENDOCRINE THERAPY	1 (0.1%)	2 (0.2%)
AROMATASE INHIBITORS	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANASTROZOLE	0	1 (0.1%)
LETROZOLE	1 (0.1%)	0
ANTI-ESTROGENS	0	1 (0.1%)
TAMOXIFEN	0	1 (0.1%)
IMMUNE SERA AND IMMUNOGLOBULINS	3 (0.3%)	0
SPECIFIC IMMUNOGLOBULINS	3 (0.3%)	0
HYPERIMMUNE PLASMA COVID-19	3 (0.3%)	0
ANTIDIARRHEALS, INTESTINAL	1 (0.1%)	1 (0.1%)
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1%)	1 (0.1%)
MESALAZINE	1 (0.1%)	1 (0.1%)
ANTIFUNGALS FOR DERMATOLOGICAL USE	0	2 (0.2%)
ANTIFUNGALS FOR SYSTEMIC USE	0	1 (0.1%)
TERBINAFINE	0	1 (0.1%)
OTHER ANTIFUNGALS FOR TOPICAL USE	0	1 (0.1%)
TOLNAFTATE	0	1 (0.1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	1 (0.1%)	1 (0.1%)
CENTRALLY ACTING ANTIOBESITY PRODUCTS	1 (0.1%)	1 (0.1%)
PHENTERMINE	1 (0.1%)	1 (0.1%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	2 (0.2%)	0

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	2 (0.2%)	0
DICYCLOVERINE	1 (0.1%)	0
TRIMEBUTINE	1 (0.1%)	0
OTHER DERMATOLOGICAL PREPARATIONS	0	2 (0.2%)
ANTIHIDROTICS	0	1 (0.1%)
GLYCOPYRRONIUM BROMIDE	0	1 (0.1%)
OTHER DERMATOLOGICALS	0	1 (0.1%)
FINASTERIDE	0	1 (0.1%)
VASOPROTECTIVES	0	2 (0.2%)
BIOFLAVONOIDS	0	2 (0.2%)
ALKA 4-COMPLEX;DIOSMIN	0	1 (0.1%)
DIOSMIN	0	1 (0.1%)
ANTIMYCOTICS FOR SYSTEMIC USE	1 (0.1%)	0
TRIAZOLE DERIVATIVES	1 (0.1%)	0
FLUCONAZOLE	1 (0.1%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	1 (0.1%)	0
ELECTROLYTE SOLUTIONS	1 (0.1%)	0
SODIUM CHLORIDE	1 (0.1%)	0
DRUGS FOR CONSTIPATION	0	1 (0.1%)
SOFTENERS, EMOLLIENTS	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DOCUSATE SODIUM	0	1 (0.1%)
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
HOMEOPATHIC PREPARATION	1 (0.1%)	0
IMMUNOSTIMULANTS	1 (0.1%)	0
COLONY STIMULATING FACTORS	1 (0.1%)	0
FILGRASTIM	1 (0.1%)	0
OTHER GYNECOLOGICALS	1 (0.1%)	0
OTHER GYNECOLOGICALS	1 (0.1%)	0
METHOTREXATE	1 (0.1%)	0
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	0	1 (0.1%)
VASOPRESSIN AND ANALOGUES	0	1 (0.1%)
DESMOPRESSIN	0	1 (0.1%)
TONICS	1 (0.1%)	0
TONICS	1 (0.1%)	0
DIETARY SUPPLEMENT	1 (0.1%)	0
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	0	1 (0.1%)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	0	1 (0.1%)
DICLOFENAC	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.3. Concomitant medications day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	1 (0.1%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	1 (0.1%)
MITRAGYNA SPECIOSA	0	1 (0.1%)
Uncoded	1 (0.1%)	0
Uncoded	1 (0.1%)	0
BLINDED THERAPY	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant medication	180 (15.1%)	157 (13.2%)
VITAMINS	63 (5.3%)	59 (4.9%)
VITAMIN D AND ANALOGUES	35 (2.9%)	33 (2.8%)
VITAMIN D NOS	21 (1.8%)	23 (1.9%)
COLECALCIFEROL	14 (1.2%)	10 (0.8%)
ERGOCALCIFEROL	1 (0.1%)	0
ASCORBIC ACID (VITAMIN C), PLAIN	27 (2.3%)	28 (2.3%)
ASCORBIC ACID	27 (2.3%)	28 (2.3%)
MULTIVITAMINS, PLAIN	17 (1.4%)	22 (1.8%)
VITAMINS NOS	16 (1.3%)	22 (1.8%)
ASCORBIC ACID;CALCIUM PANTOTHENATE;COLECALCIFEROL;CYANOCOBALAMIN ;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1 (0.1%)	0
OTHER PLAIN VITAMIN PREPARATIONS	4 (0.3%)	4 (0.3%)
BIOTIN	2 (0.2%)	1 (0.1%)
VITAMIN B NOS	1 (0.1%)	1 (0.1%)
NICOTINAMIDE	1 (0.1%)	0
TOCOPHERYL ACETATE	0	1 (0.1%)
VITAMIN E NOS	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
MULTIVITAMINS WITH MINERALS	3 (0.3%)	4 (0.3%)
MINERALS NOS;VITAMINS NOS	3 (0.3%)	3 (0.3%)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID;	0	1 (0.1%)
COMBINATIONS OF VITAMINS	3 (0.3%)	0
COLECALCIFEROL;MENAQUINONE-7	1 (0.1%)	0
COLECALCIFEROL;RETINOL;TOCOPHEROL	1 (0.1%)	0
VITAMINS NOS	1 (0.1%)	0
VITAMINS, OTHER COMBINATIONS	2 (0.2%)	1 (0.1%)
ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM;MANGANES E;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	2 (0.2%)	1 (0.1%)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.1%)	1 (0.1%)
MINERALS NOS;VITAMINS NOS	1 (0.1%)	1 (0.1%)
VITAMIN A, PLAIN	1 (0.1%)	1 (0.1%)
VITAMIN A NOS	1 (0.1%)	1 (0.1%)
VITAMIN B-COMPLEX, PLAIN	2 (0.2%)	0
VITAMIN B NOS	2 (0.2%)	0
VITAMIN B1, PLAIN	1 (0.1%)	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SULBUTIAMINE	0	1 (0.1%)
THIAMINE HYDROCHLORIDE	1 (0.1%)	0
VITAMIN A AND D IN COMBINATION	1 (0.1%)	0
COD-LIVER OIL	1 (0.1%)	0
VITAMINS WITH MINERALS	1 (0.1%)	0
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID;	1 (0.1%)	0
ANTITHROMBOTIC AGENTS	49 (4.1%)	29 (2.4%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	41 (3.4%)	27 (2.3%)
ACETYLSALICYLIC ACID	40 (3.4%)	26 (2.2%)
CLOPIDOGREL	1 (0.1%)	1 (0.1%)
HEPARIN GROUP	8 (0.7%)	1 (0.1%)
ENOXAPARIN SODIUM	6 (0.5%)	0
ENOXAPARIN	2 (0.2%)	1 (0.1%)
DIRECT FACTOR XA INHIBITORS	5 (0.4%)	1 (0.1%)
APIXABAN	4 (0.3%)	1 (0.1%)
RIVAROXABAN	1 (0.1%)	0
MINERAL SUPPLEMENTS	27 (2.3%)	29 (2.4%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ZINC	17 (1.4%)	21 (1.8%)
ZINC	17 (1.4%)	21 (1.8%)
MAGNESIUM	7 (0.6%)	4 (0.3%)
MAGNESIUM	5 (0.4%)	3 (0.3%)
MAGNESIUM OXIDE	2 (0.2%)	0
MAGNESIUM CHLORIDE	0	1 (0.1%)
MAGNESIUM CITRATE	0	1 (0.1%)
MAGNESIUM MALATE	0	1 (0.1%)
CALCIUM	3 (0.3%)	5 (0.4%)
CALCIUM	3 (0.3%)	4 (0.3%)
CALCIUM CARBONATE	0	1 (0.1%)
POTASSIUM	5 (0.4%)	2 (0.2%)
POTASSIUM	2 (0.2%)	2 (0.2%)
POTASSIUM CHLORIDE	3 (0.3%)	0
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	2 (0.2%)	1 (0.1%)
CALCIUM CARBONATE;COLECALCIFEROL	0	1 (0.1%)
CALCIUM CITRATE;COLECALCIFEROL	1 (0.1%)	0
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1%)	0
OTHER MINERAL PRODUCTS	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
STRONTIUM	1 (0.1%)	0
ANALGESICS	19 (1.6%)	23 (1.9%)
ANILIDES	18 (1.5%)	19 (1.6%)
PARACETAMOL	17 (1.4%)	18 (1.5%)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.1%)	0
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYL EPHRINE HYDROCHLORIDE	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (0.1%)	0
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRIN E	0	1 (0.1%)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	0	2 (0.2%)
CODEINE;PARACETAMOL	0	1 (0.1%)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	0	1 (0.1%)
OTHER OPIOIDS	1 (0.1%)	1 (0.1%)
TRAMADOL	1 (0.1%)	1 (0.1%)
OTHER ANALGESICS AND ANTIPYRETICS	0	1 (0.1%)
GABAPENTIN	0	1 (0.1%)
OTHER ANTIMIGRAINE PREPARATIONS	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
TOPIRAMATE	0	1 (0.1%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	19 (1.6%)	20 (1.7%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	12 (1.0%)	9 (0.8%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	5 (0.4%)	1 (0.1%)
ETHINYLESTRADIOL;NORGESTIMATE	2 (0.2%)	4 (0.3%)
DROSPIRENONE;ETHINYLESTRADIOL	2 (0.2%)	1 (0.1%)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	0	3 (0.3%)
ETHINYLESTRADIOL;LEVONORGESTREL	2 (0.2%)	0
DROSPIRENONE;ETHINYLESTRADIOL BETADEX CLATHRATE	1 (0.1%)	0
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	1 (0.1%)	6 (0.5%)
ESTRADIOL	1 (0.1%)	4 (0.3%)
ETHINYLESTRADIOL	0	2 (0.2%)
PROGESTOGENS	2 (0.2%)	5 (0.4%)
LEVONORGESTREL	2 (0.2%)	1 (0.1%)
ETONOGESTREL	0	2 (0.2%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.1%)
NORETHISTERONE	0	1 (0.1%)
-OXOANDROSTEN (4) DERIVATIVES	2 (0.2%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
TESTOSTERONE	2 (0.2%)	1 (0.1%)
TESTOSTERONE ENANTHATE	0	1 (0.1%)
PREGNEN (4) DERIVATIVES	1 (0.1%)	1 (0.1%)
PROGESTERONE	1 (0.1%)	1 (0.1%)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS	1 (0.1%)	1 (0.1%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	1 (0.1%)	1 (0.1%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	14 (1.2%)	12 (1.0%)
PROPIONIC ACID DERIVATIVES	12 (1.0%)	10 (0.8%)
IBUPROFEN	10 (0.8%)	8 (0.7%)
NAPROXEN	2 (0.2%)	1 (0.1%)
NAPROXEN SODIUM	0	1 (0.1%)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	2 (0.2%)	1 (0.1%)
COLLAGEN	1 (0.1%)	0
GLUCOSAMINE	0	1 (0.1%)
GLUCOSAMINE SULFATE	1 (0.1%)	0
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	0	1 (0.1%)
DICLOFENAC POTASSIUM	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	0	1 (0.1%)
CURCUMA LONGA	0	1 (0.1%)
OXICAMS	1 (0.1%)	0
MELOXICAM	1 (0.1%)	0
LIPID MODIFYING AGENTS	9 (0.8%)	13 (1.1%)
OTHER LIPID MODIFYING AGENTS	6 (0.5%)	10 (0.8%)
FISH OIL	4 (0.3%)	5 (0.4%)
OMEGA-3 NOS	1 (0.1%)	4 (0.3%)
ALIROCUMAB	1 (0.1%)	0
EICOSAPENTAENOIC ACID ETHYL ESTER	0	1 (0.1%)
EVOLOCUMAB	0	1 (0.1%)
HMG COA REDUCTASE INHIBITORS	4 (0.3%)	1 (0.1%)
SIMVASTATIN	1 (0.1%)	1 (0.1%)
ATORVASTATIN	1 (0.1%)	0
PRAVASTATIN	1 (0.1%)	0
ROSUVASTATIN CALCIUM	1 (0.1%)	0
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	0	1 (0.1%)
MONASCUS PURPUREUS	0	1 (0.1%)
NICOTINIC ACID AND DERIVATIVES	0	1 (0.1%)
NICOTINIC ACID	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIBACTERIALS FOR SYSTEMIC USE	5 (0.4%)	9 (0.8%)
MACROLIDES	3 (0.3%)	4 (0.3%)
AZITHROMYCIN	2 (0.2%)	4 (0.3%)
CLARITHROMYCIN	1 (0.1%)	0
PENICILLINS WITH EXTENDED SPECTRUM	0	2 (0.2%)
AMOXICILLIN	0	1 (0.1%)
AMPICILLIN	0	1 (0.1%)
TETRACYCLINES	1 (0.1%)	1 (0.1%)
DOXYCYCLINE	1 (0.1%)	1 (0.1%)
THIRD-GENERATION CEPHALOSPORINS	1 (0.1%)	1 (0.1%)
CEFDINIR	1 (0.1%)	1 (0.1%)
ANTIBACTERIALS FOR SYSTEMIC USE	0	1 (0.1%)
PENICILLIN NOS	0	1 (0.1%)
FIRST-GENERATION CEPHALOSPORINS	0	1 (0.1%)
CEFALEXIN	0	1 (0.1%)
IMIDAZOLE DERIVATIVES	0	1 (0.1%)
METRONIDAZOLE	0	1 (0.1%)
INTERMEDIATE-ACTING SULFONAMIDES	0	1 (0.1%)
SULFAMETHOXAZOLE	0	1 (0.1%)
TRIMETHOPRIM AND DERIVATIVES	0	1 (0.1%)
TRIMETHOPRIM	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
VACCINES	5 (0.4%)	8 (0.7%)
OTHER VIRAL VACCINES	5 (0.4%)	6 (0.5%)
COVID-19 VACCINE	5 (0.4%)	6 (0.5%)
INFLUENZA VACCINES	0	2 (0.2%)
INFLUENZA VACCINE	0	1 (0.1%)
INFLUENZA VACCINE INACT SPLIT 4V	0	1 (0.1%)
ANTIHISTAMINES FOR SYSTEMIC USE	4 (0.3%)	6 (0.5%)
PIPERAZINE DERIVATIVES	2 (0.2%)	3 (0.3%)
CETIRIZINE HYDROCHLORIDE	1 (0.1%)	3 (0.3%)
CETIRIZINE	1 (0.1%)	0
AMINOALKYL ETHERS	0	3 (0.3%)
DOXYLAMINE SUCCINATE	0	2 (0.2%)
DIPHENHYDRAMINE	0	1 (0.1%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.2%)	0
LORATADINE	2 (0.2%)	0
OTHER GYNECOLOGICALS	4 (0.3%)	5 (0.4%)
INTRAUTERINE CONTRACEPTIVES	4 (0.3%)	5 (0.4%)
LEVONORGESTREL	4 (0.3%)	4 (0.3%)
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (0.1%)
PSYCHOLEPTICS	4 (0.3%)	5 (0.4%)
BENZODIAZEPINE DERIVATIVES	2 (0.2%)	3 (0.3%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ALPRAZOLAM	0	2 (0.2%)
BROMAZEPAM	1 (0.1%)	0
CLONAZEPAM	1 (0.1%)	0
TEMAZEPAM	0	1 (0.1%)
MELATONIN RECEPTOR AGONISTS	2 (0.2%)	2 (0.2%)
MELATONIN	2 (0.2%)	2 (0.2%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.3%)	5 (0.4%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (0.3%)	5 (0.4%)
SAMBUCUS NIGRA	0	2 (0.2%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.1%)	1 (0.1%)
WITHANIA SOMNIFERA	0	2 (0.2%)
BACOPA MONNIERI	1 (0.1%)	0
CURCUMA LONGA RHIZOME	1 (0.1%)	0
MALUS SPP. VINEGAR EXTRACT	1 (0.1%)	0
PRUNUS CERASUS	1 (0.1%)	0
TRIGONELLA FOENUM-GRAECUM	0	1 (0.1%)
VALERIANA OFFICINALIS ROOT	0	1 (0.1%)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	4 (0.3%)	4 (0.3%)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	4 (0.3%)	4 (0.3%)
PROBIOTICS NOS	2 (0.2%)	2 (0.2%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
QUERCETIN	2 (0.2%)	2 (0.2%)
ANTIANEMIC PREPARATIONS	5 (0.4%)	2 (0.2%)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	3 (0.3%)	2 (0.2%)
VITAMIN B12 NOS	3 (0.3%)	2 (0.2%)
IRON BIVALENT, ORAL PREPARATIONS	3 (0.3%)	0
ASCORBIC ACID;FERROUS FUMARATE	1 (0.1%)	0
FERROUS GLUCONATE	1 (0.1%)	0
FERROUS SULFATE	1 (0.1%)	0
IRON IN OTHER COMBINATIONS	0	1 (0.1%)
FERRIC AMMONIUM CITRATE;FOLIC ACID;VITAMIN B12 NOS	0	1 (0.1%)
COUGH AND COLD PREPARATIONS	2 (0.2%)	5 (0.4%)
EXPECTORANTS	1 (0.1%)	3 (0.3%)
GUAIFENESIN	1 (0.1%)	3 (0.3%)
OPIUM ALKALOIDS AND DERIVATIVES	0	2 (0.2%)
DEXTROMETHORPHAN	0	1 (0.1%)
DEXTROMETHORPHAN HYDROBROMIDE	0	1 (0.1%)
HERBAL DIAPHORETICS AND OTHER HERBAL COUGH AND COLD REMEDIES	0	1 (0.1%)
SAMBUCUS NIGRA	0	1 (0.1%)
MUCOLYTICS	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29
Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ACETYLCYSTEINE	0	1 (0.1%)
OPIUM DERIVATIVES AND EXPECTORANTS	1 (0.1%)	0
CODEINE;GUAIFENESIN	1 (0.1%)	0
PSYCHOANALEPTICS	5 (0.4%)	2 (0.2%)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	2 (0.2%)	1 (0.1%)
ESCITALOPRAM OXALATE	1 (0.1%)	0
FLUOXETINE	0	1 (0.1%)
SERTRALINE HYDROCHLORIDE	1 (0.1%)	0
OTHER ANTIDEPRESSANTS	2 (0.2%)	0
TRAZODONE	2 (0.2%)	0
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.1%)	0
ATOMOXETINE	1 (0.1%)	0
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	0	1 (0.1%)
AMITRIPTYLINE	0	1 (0.1%)
DRUGS FOR ACID RELATED DISORDERS	4 (0.3%)	2 (0.2%)
PROTON PUMP INHIBITORS	2 (0.2%)	2 (0.2%)
ESOMEPRAZOLE	0	1 (0.1%)
LANSOPRAZOLE	1 (0.1%)	0
OMEPRAZOLE	1 (0.1%)	0
PANTOPRAZOLE	0	1 (0.1%)
H2-RECEPTOR ANTAGONISTS	2 (0.2%)	0

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
FAMOTIDINE	2 (0.2%)	0
DRUGS FOR CONSTIPATION	4 (0.3%)	2 (0.2%)
SOFTENERS, EMOLLIENTS	3 (0.3%)	0
DOCUSATE SODIUM	2 (0.2%)	0
DOCUSATE	1 (0.1%)	0
BULK-FORMING LAXATIVES	0	2 (0.2%)
METHYLCELLULOSE	0	1 (0.1%)
POLYCARBOPHIL	0	1 (0.1%)
OSMOTICALLY ACTING LAXATIVES	2 (0.2%)	0
MAGNESIUM HYDROXIDE	2 (0.2%)	0
LACTULOSE	1 (0.1%)	0
CONTACT LAXATIVES	1 (0.1%)	0
BISACODYL	1 (0.1%)	0
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.3%)	2 (0.2%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	3 (0.3%)	1 (0.1%)
LOSARTAN	3 (0.3%)	0
OLMESARTAN MEDOXOMIL	0	1 (0.1%)
ACE INHIBITORS, PLAIN	0	1 (0.1%)
LISINAPRIL	0	1 (0.1%)
CARDIAC THERAPY	4 (0.3%)	1 (0.1%)
OTHER CARDIAC PREPARATIONS	3 (0.3%)	0

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
UBIDECARENONE	3 (0.3%)	0
ADRENERGIC AND DOPAMINERGIC AGENTS	0	1 (0.1%)
EPINEPHRINE	0	1 (0.1%)
ORGANIC NITRATES	1 (0.1%)	0
GLYCERYL TRINITRATE	1 (0.1%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	4 (0.3%)	0
ELECTROLYTE SOLUTIONS	2 (0.2%)	0
MAGNESIUM SULFATE	2 (0.2%)	0
POTASSIUM CHLORIDE	2 (0.2%)	0
SODIUM CHLORIDE	2 (0.2%)	0
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1 (0.1%)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	2 (0.2%)	0
GLUCOSE;SODIUM CHLORIDE	1 (0.1%)	0
POTASSIUM	1 (0.1%)	0
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	1 (0.1%)	3 (0.3%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	0	1 (0.1%)
BUDESONIDE;FORMOTEROL FUMARATE	0	1 (0.1%)
GLUCOCORTICOIDS	0	1 (0.1%)
BECLOMETASONE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
LEUKOTRIENE RECEPTOR ANTAGONISTS	0	1 (0.1%)
MONTELUKAST	0	1 (0.1%)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	1 (0.1%)	0
SALBUTAMOL SULFATE	1 (0.1%)	0
ANTIDIARRHEALS, INTESTINAL	3 (0.3%)	0
ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
ANTIDIARRHEAL MICROORGANISMS	2 (0.2%)	0
BIFIDOBACTERIUM LACTIS;INULIN;LACTOBACILLUS	1 (0.1%)	0
ACIDOPHILUS;LACTOBACILLUS		
PARACASEI;SACCHAROMYCES		
BOULARDII;TRANS-GALACTOOLIGOSACCHARIDE		
PROBIOTICS NOS	1 (0.1%)	0
ORAL REHYDRATION SALT FORMULATIONS	1 (0.1%)	0
ELECTROLYTES NOS;GLUCOSE	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	2 (0.2%)
NEURAMINIDASE INHIBITORS	0	1 (0.1%)
OSELTAMIVIR	0	1 (0.1%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE	0	1 (0.1%)
TRANSCRIPTASE INHIBITORS		
ACICLOVIR	0	1 (0.1%)
OTHER ANTIVIRALS	1 (0.1%)	0
THYMALFASIN	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
NASAL PREPARATIONS	1 (0.1%)	2 (0.2%)
OTHER NASAL PREPARATIONS	1 (0.1%)	1 (0.1%)
MUPIROCIN	1 (0.1%)	0
SODIUM CHLORIDE;XYLITOL	0	1 (0.1%)
SYMPATHOMIMETICS	0	1 (0.1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.1%)
OTHER NERVOUS SYSTEM DRUGS	1 (0.1%)	2 (0.2%)
DRUGS USED IN NICOTINE DEPENDENCE	1 (0.1%)	0
BUPROPION	1 (0.1%)	0
DRUGS USED IN OPIOID DEPENDENCE	0	1 (0.1%)
NALTREXONE	0	1 (0.1%)
OTHER PARASYMPATHOMIMETICS	0	1 (0.1%)
CEVIMELINE	0	1 (0.1%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.1%)	1 (0.1%)
MEDICAL GASES	1 (0.1%)	0
OXYGEN	1 (0.1%)	0
OTHER THERAPEUTIC PRODUCTS	0	1 (0.1%)
CHLOROPHYLL	0	1 (0.1%)
ANTIEMETICS AND ANTINAUSEANTS	1 (0.1%)	1 (0.1%)
OTHER ANTIEMETICS	0	1 (0.1%)
PROMETHAZINE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
SEROTONIN (5HT3) ANTAGONISTS	1 (0.1%)	0
ONDANSETRON	1 (0.1%)	0
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1%)	1 (0.1%)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	0	1 (0.1%)
TRIAMCINOLONE	0	1 (0.1%)
CORTICOSTEROIDS, POTENT (GROUP III)	1 (0.1%)	0
BETAMETHASONE	1 (0.1%)	0
ENDOCRINE THERAPY	1 (0.1%)	1 (0.1%)
AROMATASE INHIBITORS	1 (0.1%)	1 (0.1%)
,3'-DIINDOLYLMET HANE	0	1 (0.1%)
LETROZOLE	1 (0.1%)	0
IMMUNOSTIMULANTS	2 (0.2%)	0
HERBAL IMMUNOMODULATORS	2 (0.2%)	0
ASCORBIC ACID;CALCIUM;CORDYCEPS SINENSIS;GANODERMA LUCIDUM;GRIFOLA FRONDOSA;HERICIUM ERINACEUS;VITAMIN D NOS	1 (0.1%)	0
ECHINACEA SPP.	1 (0.1%)	0
OPHTHALMOLOGICALS	1 (0.1%)	1 (0.1%)
ANTIBIOTICS	0	1 (0.1%)
ERYTHROMYCIN	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIINFLAMMATORY AGENTS, NON-STEROIDS	0	1 (0.1%)
KETOROLAC	0	1 (0.1%)
OTHER OPHTHALMOLOGICALS	1 (0.1%)	0
CARMELLOSE	1 (0.1%)	0
CARMELLOSE SODIUM	1 (0.1%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	2 (0.2%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.1%)	0
AMINO ACIDS NOS;ANIMAL UNSPECIFIED;ASCORBIC ACID;CYANOCOBALAMIN;HERBAL NOS;MANGANESE;PHOSPHORUS;RETINOL PALMITATE;TOCOPHEROL	1 (0.1%)	0
QUININE AND DERIVATIVES	1 (0.1%)	0
QUININE	1 (0.1%)	0
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.1%)
ASCORBIC ACID	0	1 (0.1%)
ANABOLIC AGENTS FOR SYSTEMIC USE	0	1 (0.1%)
ANDROSTAN DERIVATIVES	0	1 (0.1%)
PRASTERONE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other

Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	1 (0.1%)	0
OTHER ANTIBIOTICS FOR TOPICAL USE	1 (0.1%)	0
BACITRACIN	1 (0.1%)	0
ANTIGOUT PREPARATIONS	0	1 (0.1%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	0	1 (0.1%)
ALLOPURINOL	0	1 (0.1%)
ANTIHYPERTENSIVES	0	1 (0.1%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	0	1 (0.1%)
PRAZOSIN	0	1 (0.1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	1 (0.1%)	0
CENTRALLY ACTING ANTIOBESITY PRODUCTS	1 (0.1%)	0
PHENTERMINE	1 (0.1%)	0
ANTIPSORIATICS	1 (0.1%)	0
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (0.1%)	0
CALCIPOTRIOL	1 (0.1%)	0
BETA BLOCKING AGENTS	1 (0.1%)	0
BETA BLOCKING AGENTS, SELECTIVE	1 (0.1%)	0
METOPROLOL	1 (0.1%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	1 (0.1%)	0
GLUCOCORTICOIDS	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29

Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
DEXAMETHASONE	1 (0.1%)	0
DIGESTIVES, INCL. ENZYMES	0	1 (0.1%)
HERBAL DIGESTIVES, OTHER	0	1 (0.1%)
SILYBUM MARIANUM	0	1 (0.1%)
DRUGS USED IN DIABETES	1 (0.1%)	0
BIGUANIDES	1 (0.1%)	0
METFORMIN	1 (0.1%)	0
EMOLLIENTS AND PROTECTIVES	1 (0.1%)	0
ZINC PRODUCTS	1 (0.1%)	0
MENTHOL;ZINC OXIDE	1 (0.1%)	0
OTHER DERMATOLOGICAL PREPARATIONS	0	1 (0.1%)
OTHER DERMATOLOGICALS	0	1 (0.1%)
DICLOFENAC SODIUM	0	1 (0.1%)
THYROID THERAPY	0	1 (0.1%)
IODINE THERAPY	0	1 (0.1%)
ASCORBIC ACID;COPPER GLUCONATE;CYANOCOBALAMIN;FERROUS GLUCONATE;FOLIC ACID;IODINE;MAGNESIUM CITRATE;MANGANESE CITRATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;SELENOMETHIONINE;TYROSINE;ZINC CITRATE	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.4. Concomitant medications day 1 to day 29
Indication Reason: Other
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
TONICS	0	1 (0.1%)
HERBAL TONICS, OTHER	0	1 (0.1%)
MORINGA OLEIFERA	0	1 (0.1%)
UROLOGICALS	1 (0.1%)	0
DRUGS USED IN ERECTILE DYSFUNCTION	1 (0.1%)	0
SILDENAFIL CITRATE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant medication	10 (0.8%)	18 (1.5%)
ANTITHROMBOTIC AGENTS	3 (0.3%)	9 (0.8%)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	3 (0.3%)	9 (0.8%)
ACETYLSALICYLIC ACID	3 (0.3%)	8 (0.7%)
CLOPIDOGREL	0	1 (0.1%)
CLOPIDOGREL BISULFATE	0	1 (0.1%)
VITAMINS	1 (0.1%)	4 (0.3%)
VITAMIN D AND ANALOGUES	1 (0.1%)	3 (0.3%)
COLECALCIFEROL	0	2 (0.2%)
VITAMIN D NOS	1 (0.1%)	1 (0.1%)
MULTIVITAMINS, PLAIN	1 (0.1%)	1 (0.1%)
VITAMINS NOS	1 (0.1%)	1 (0.1%)
ASCORBIC ACID (VITAMIN C), PLAIN	0	1 (0.1%)
ASCORBIC ACID	0	1 (0.1%)
VITAMIN B-COMPLEX, PLAIN	1 (0.1%)	0
VITAMIN B COMPLEX	1 (0.1%)	0
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	1 (0.1%)	1 (0.1%)
ACE INHIBITORS, PLAIN	1 (0.1%)	0
ENALAPRIL	1 (0.1%)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	0	1 (0.1%)
LOSARTAN	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (0.1%)	1 (0.1%)
OXICAMS	0	1 (0.1%)
MELOXICAM	0	1 (0.1%)
PROPIONIC ACID DERIVATIVES	1 (0.1%)	0
IBUPROFEN	1 (0.1%)	0
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1%)	1 (0.1%)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1%)	1 (0.1%)
EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	1 (0.1%)	1 (0.1%)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	0	1 (0.1%)
VALACICLOVIR HYDROCHLORIDE	0	1 (0.1%)
LIPID MODIFYING AGENTS	1 (0.1%)	1 (0.1%)
HMG COA REDUCTASE INHIBITORS	1 (0.1%)	1 (0.1%)
ATORVASTATIN	1 (0.1%)	0
SIMVASTATIN	0	1 (0.1%)
PSYCHOANALEPTICS	2 (0.2%)	0
OTHER ANTIDEPRESSANTS	2 (0.2%)	0
LAMOTRIGINE	2 (0.2%)	0
VENLAFAXINE HYDROCHLORIDE	1 (0.1%)	0
ANALGESICS	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
OTHER ANTIMIGRAINE PREPARATIONS	1 (0.1%)	0
VENLAFAXINE	1 (0.1%)	0
ANTIANEMIC PREPARATIONS	1 (0.1%)	0
IRON BIVALENT, ORAL PREPARATIONS	1 (0.1%)	0
IRON	1 (0.1%)	0
ANTIGOUT PREPARATIONS	0	1 (0.1%)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	0	1 (0.1%)
ALLOPURINOL	0	1 (0.1%)
ANTIHEMORRHAGICS	1 (0.1%)	0
VITAMIN K	1 (0.1%)	0
VITAMIN K NOS	1 (0.1%)	0
ANTIHISTAMINES FOR SYSTEMIC USE	0	1 (0.1%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	0	1 (0.1%)
LORATADINE	0	1 (0.1%)
CORTICOSTEROIDS FOR SYSTEMIC USE	1 (0.1%)	0
GLUCOCORTICOIDS	1 (0.1%)	0
PREDNISONE	1 (0.1%)	0
DRUGS USED IN DIABETES	0	1 (0.1%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	0	1 (0.1%)
SITAGLIPTIN	0	1 (0.1%)
SULFONYLUREAS	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
GLIBENCLAMIDE	0	1 (0.1%)
THIAZOLIDINEDIONES	0	1 (0.1%)
PIOGLITAZONE	0	1 (0.1%)
MINERAL SUPPLEMENTS	1 (0.1%)	0
MAGNESIUM	1 (0.1%)	0
MAGNESIUM	1 (0.1%)	0
MUSCLE RELAXANTS	0	1 (0.1%)
OTHER CENTRALLY ACTING AGENTS	0	1 (0.1%)
CYCLOBENZAPRINE	0	1 (0.1%)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1%)	0
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1%)	0
ASTAXANTHIN	1 (0.1%)	0
OTHER GYNECOLOGICALS	1 (0.1%)	0
INTRAVAGINAL CONTRACEPTIVES	1 (0.1%)	0
ETHINYLESTRADIOL;ETONOGESTREL	1 (0.1%)	0
PSYCHOLEPTICS	1 (0.1%)	0
BENZODIAZEPINE DERIVATIVES	1 (0.1%)	0
ALPRAZOLAM	1 (0.1%)	0
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	1 (0.1%)	0
QUETIAPINE	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 21.5. Concomitant medications day 1 to day 29
Indication Reason: Premedication
Modified Full Analysis Set

ATC Level2 ATC Level4 Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Uncoded	1 (0.1%)	0
Uncoded	1 (0.1%)	0
ADRENAL CORTICAL EXTRACT;ADRENAL GLAND;CALCIUM PANTOTHENATE;CORDYCEPS SINENSIS MYCELIUM;ELEUTHEROCOCCUS SPP.;WITHANIA SOMNIFERA ROOT	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 22.1. Concomitant procedures day 1 to day 29
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant procedure	71 (6.0%)	43 (3.6%)
Investigations	67 (5.6%)	39 (3.3%)
Physical examination	46 (3.9%)	31 (2.6%)
Chest X-ray	20 (1.7%)	5 (0.4%)
Electrocardiogram	5 (0.4%)	2 (0.2%)
Viral test	4 (0.3%)	3 (0.3%)
Computerised tomogram thorax	4 (0.3%)	1 (0.1%)
Angiogram	3 (0.3%)	1 (0.1%)
Ultrasound Doppler	3 (0.3%)	0
X-ray	0	3 (0.3%)
Abdominal X-ray	2 (0.2%)	0
Blood test	0	1 (0.1%)
C-reactive protein	0	1 (0.1%)
Computerised tomogram	0	1 (0.1%)
Computerised tomogram abdomen	1 (0.1%)	0
Computerised tomogram head	0	1 (0.1%)
Echocardiogram	1 (0.1%)	0
Fibrin D dimer	0	1 (0.1%)
Flow cytometry	0	1 (0.1%)
Serum ferritin	0	1 (0.1%)
Ultrasound scan	1 (0.1%)	0
X-ray gastrointestinal tract	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 22.1. Concomitant procedures day 1 to day 29
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
X-ray with contrast upper gastrointestinal tract	1 (0.1%)	0
Surgical and medical procedures	8 (0.7%)	6 (0.5%)
Mechanical ventilation	3 (0.3%)	1 (0.1%)
Endotracheal intubation	2 (0.2%)	0
Angioplasty	0	1 (0.1%)
Arterial catheterisation	1 (0.1%)	0
Bilevel positive airway pressure	1 (0.1%)	0
Cautery to nose	1 (0.1%)	0
Central venous catheterisation	1 (0.1%)	0
Chemical peel of skin	0	1 (0.1%)
Cholecystectomy	1 (0.1%)	0
Coronary arterial stent insertion	0	1 (0.1%)
Dialysis	1 (0.1%)	0
Duodenostomy	1 (0.1%)	0
Enterorrhaphy	1 (0.1%)	0
Explorative laparotomy	1 (0.1%)	0
Eye operation	0	1 (0.1%)
Gastrointestinal tube insertion	1 (0.1%)	0
Incisional drainage	0	1 (0.1%)
Physiotherapy	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 22.2. Concomitant procedures day 1 to day 29
Indication Reason: Medical History
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant procedure	4 (0.3%)	0
Investigations	3 (0.3%)	0
Chest X-ray	2 (0.2%)	0
Angiogram	1 (0.1%)	0
Surgical and medical procedures	1 (0.1%)	0
Mechanical ventilation	1 (0.1%)	0

Clinical cut-off: 19Aug2021

Table 22.3. Concomitant procedures day 1 to day 29
Indication Reason: Adverse Event
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant procedure	21 (1.8%)	12 (1.0%)
Investigations	18 (1.5%)	10 (0.8%)
Chest X-ray	15 (1.3%)	5 (0.4%)
Electrocardiogram	4 (0.3%)	2 (0.2%)
Computerised tomogram thorax	4 (0.3%)	1 (0.1%)
Angiogram	2 (0.2%)	1 (0.1%)
X-ray	0	3 (0.3%)
Physical examination	2 (0.2%)	0
Ultrasound Doppler	2 (0.2%)	0
Abdominal X-ray	1 (0.1%)	0
Blood test	0	1 (0.1%)
C-reactive protein	0	1 (0.1%)
Computerised tomogram	0	1 (0.1%)
Computerised tomogram abdomen	1 (0.1%)	0
Computerised tomogram head	0	1 (0.1%)
Echocardiogram	1 (0.1%)	0
Fibrin D dimer	0	1 (0.1%)
Flow cytometry	0	1 (0.1%)
Serum ferritin	0	1 (0.1%)
X-ray gastrointestinal tract	1 (0.1%)	0
X-ray with contrast upper gastrointestinal tract	1 (0.1%)	0
Surgical and medical procedures	5 (0.4%)	3 (0.3%)

Clinical cut-off: 19Aug2021

Table 22.3. Concomitant procedures day 1 to day 29
Indication Reason: Adverse Event
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Mechanical ventilation	2 (0.2%)	1 (0.1%)
Endotracheal intubation	2 (0.2%)	0
Angioplasty	0	1 (0.1%)
Arterial catheterisation	1 (0.1%)	0
Bilevel positive airway pressure	1 (0.1%)	0
Central venous catheterisation	1 (0.1%)	0
Cholecystectomy	1 (0.1%)	0
Coronary arterial stent insertion	0	1 (0.1%)
Dialysis	1 (0.1%)	0
Enterorrhaphy	1 (0.1%)	0
Explorative laparotomy	1 (0.1%)	0
Gastrointestinal tube insertion	1 (0.1%)	0
Incisional drainage	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 22.4. Concomitant procedures day 1 to day 29
Indication Reason: Disease under study
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant procedure	46 (3.9%)	29 (2.4%)
Investigations	46 (3.9%)	28 (2.3%)
Physical examination	45 (3.8%)	28 (2.3%)
Viral test	4 (0.3%)	3 (0.3%)
Chest X-ray	1 (0.1%)	0
Surgical and medical procedures	0	1 (0.1%)
Physiotherapy	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 22.5. Concomitant procedures day 1 to day 29
Indication Reason: Other
Modified Full Analysis Set

Primary System Organ Class Preferred Term	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Subjects with at least one concomitant procedure	6 (0.5%)	5 (0.4%)
Investigations	6 (0.5%)	3 (0.3%)
Physical examination	1 (0.1%)	3 (0.3%)
Chest X-ray	2 (0.2%)	0
Ultrasound Doppler	2 (0.2%)	0
Abdominal X-ray	1 (0.1%)	0
Electrocardiogram	1 (0.1%)	0
Ultrasound scan	1 (0.1%)	0
Surgical and medical procedures	2 (0.2%)	2 (0.2%)
Cautery to nose	1 (0.1%)	0
Chemical peel of skin	0	1 (0.1%)
Duodenostomy	1 (0.1%)	0
Eye operation	0	1 (0.1%)

Clinical cut-off: 19Aug2021

Table 23. Summary of Risk Factors for Severe COVID-19
Phase 3 Cohort 1 with ≥ 1 Risk Factor for Severe COVID-19 post PA6
Modified Full Analysis Set

	Placebo (N=1193)	Casirivimab/Imdevimab (N=1192)
Risk factors for Severe COVID-19		
Age ≥ 50 years	565 (47.36%)	594 (49.83%)
Obesity, defined as BMI ≥ 30	705 (59.09%)	687 (57.63%)
Cardiovascular disease, including hypertension	418 (35.04%)	439 (36.83%)
Chronic lung disease, including asthma	209 (17.52%)	200 (16.78%)
Type 1 or type 2 diabetes mellitus	153 (12.82%)	144 (12.08%)
Chronic kidney disease, including those on dialysis	9 (0.75%)	11 (0.92%)
Chronic liver disease	5 (0.42%)	8 (0.67%)
Immunocompromised	17 (1.42%)	32 (2.68%)
Immunosuppressed	17 (1.42%)	32 (2.68%)
Taking Immunosuppressants	0 (0.00%)	0 (0.00%)

Clinical cut-off: 19Aug2021

Datenschnitt 19.08.2021 (DCO2)

Verträglichkeit

Hauptdokumente

POPULATION: Safety
 ENDPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	129	9,7	1332	100	163	12,2	0,77	Algorithm converged.	0,6	0,98	-2,531	Algorithm converged.	-4,9	-0,16	0,79	Algorithm converged.	0,64	0,99	0,0368		1,26	Algorithm converged.	1,01	1,57
Sex	Male	641	48,2	56	8,7	634	47,6	75	11,8	0,71	Algorithm converged.	0,5	1,03	-3,093	Algorithm converged.	-6,42	0,24	0,74	Algorithm converged.	0,53	1,03	0,069	0,5596	1,35	Algorithm converged.	0,98	1,88
	Female	688	51,8	73	10,6	698	52,4	88	12,6	0,82	Algorithm converged.	0,59	1,14	-1,997	Algorithm converged.	-5,37	1,37	0,84	Algorithm converged.	0,63	1,13	0,2462		1,19	Algorithm converged.	0,89	1,59
Age	18-64	1168	87,9	104	8,9	1183	88,8	122	10,3	0,85	Algorithm converged.	0,65	1,12	-1,409	Algorithm converged.	-3,79	0,97	0,86	Algorithm converged.	0,67	1,11	0,2467	0,0389	1,16	Algorithm converged.	0,9	1,49
	65-74	110	8,3	19	17,3	114	8,6	27	23,7	0,67	Algorithm converged.	0,35	1,3	-6,411	Algorithm converged.	-16,94	4,12	0,73	Algorithm converged.	0,43	1,23	0,2361		1,37	Algorithm converged.	0,81	2,32
	>=75	51	3,8	6	11,8	35	2,6	14	40	0,2	Algorithm converged.	0,07	0,59	-28,235	Algorithm converged.	-46,72	-9,75	0,29	Algorithm converged.	0,13	0,69	0,0025		3,4	Algorithm converged.	1,45	7,99
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	35	9,5	360	27	32	8,9	1,07	Algorithm converged.	0,65	1,77	0,571	Algorithm converged.	-3,62	4,76	1,06	Algorithm converged.	0,67	1,68	0,7896	0,0223	0,94	Algorithm converged.	0,6	1,48
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	15	9,6	183	13,7	19	10,4	0,91	Algorithm converged.	0,45	1,86	-0,828	Algorithm converged.	-7,21	5,55	0,92	Algorithm converged.	0,48	1,75	0,7999		1,09	Algorithm converged.	0,57	2,07
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	11	6	205	15,4	36	17,6	0,3	Algorithm converged.	0,15	0,61	-11,55	Algorithm converged.	-17,79	-5,31	0,34	Algorithm converged.	0,18	0,65	0,0005		2,92	Algorithm converged.	1,53	5,57
	>10 ⁷ copies/mL	590	44,4	67	11,4	561	42,1	75	13,4	0,83	Algorithm converged.	0,58	1,18	-2,013	Algorithm converged.	-5,82	1,79	0,85	Algorithm converged.	0,62	1,16	0,2995		1,18	Algorithm converged.	0,86	1,6
	Unknown	29	2,2	1	3,4	23	1,7	1	4,3	0,79	Algorithm converged.	0,05	13,28	-0,9	Algorithm converged.	-11,56	9,76	0,79	Algorithm converged.	0,05	12,01	1		1,26	Algorithm converged.	0,08	19,09
Country	USA	1237	93,1	124	10	1239	93	153	12,3	0,79	Algorithm converged.	0,62	1,02	-2,324	Algorithm converged.	-4,81	0,16	0,81	Algorithm converged.	0,65	1,01	0,0666	0,3689	1,23	Algorithm converged.	0,99	1,54
	MEX	92	6,9	5	5,4	93	7	10	10,8	0,48	Algorithm converged.	0,16	1,45	-5,318	Algorithm converged.	-13,13	2,5	0,51	Algorithm converged.	0,18	1,42	0,2813		1,98	Algorithm converged.	0,7	5,56

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-1-ae-raw-anyae

POPULATION: Safety
 ENDPOINT: Any AEs (excluding disease related events)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	1329	100	121	9,1	1332	100	140	10,5	0,85	Algorithm converged.	0,66	1,1	-1,406	Algorithm converged.	-3,67	0,85	0,87	Algorithm converged.	0,69	1,09	0,2229		1,15	Algorithm converged.	0,92	1,45
Sex	Male	641	48,2	52	8,1	634	47,6	63	9,9	0,8	Algorithm converged.	0,54	1,18	-1,825	Algorithm converged.	-4,97	1,32	0,82	Algorithm converged.	0,58	1,16	0,2557	0,6508	1,22	Algorithm converged.	0,86	1,74
	Female	688	51,8	69	10	698	52,4	77	11	0,9	Algorithm converged.	0,64	1,27	-1,002	Algorithm converged.	-4,23	2,23	0,91	Algorithm converged.	0,67	1,24	0,5434		1,1	Algorithm converged.	0,81	1,5
Age	18-64	1168	87,9	99	8,5	1183	88,8	106	9	0,94	Algorithm converged.	0,71	1,25	-0,484	Algorithm converged.	-2,76	1,8	0,95	Algorithm converged.	0,73	1,23	0,6774	0,0658	1,06	Algorithm converged.	0,81	1,37
	65-74	110	8,3	17	15,5	114	8,6	23	20,2	0,72	Algorithm converged.	0,36	1,44	-4,721	Algorithm converged.	-14,72	5,27	0,77	Algorithm converged.	0,43	1,35	0,3575		1,31	Algorithm converged.	0,74	2,31
	>=75	51	3,8	5	9,8	35	2,6	11	31,4	0,24	Algorithm converged.	0,07	0,76	-21,625	Algorithm converged.	-39,04	-4,21	0,31	Algorithm converged.	0,12	0,82	0,0218		3,21	Algorithm converged.	1,22	8,42
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	33	8,9	360	27	27	7,5	1,21	Algorithm converged.	0,71	2,05	1,419	Algorithm converged.	-2,56	5,4	1,19	Algorithm converged.	0,73	1,94	0,4856	0,0344	0,84	Algorithm converged.	0,52	1,37
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	14	8,9	183	13,7	17	9,3	0,96	Algorithm converged.	0,46	2,01	-0,372	Algorithm converged.	-6,5	5,76	0,96	Algorithm converged.	0,49	1,88	0,9055		1,04	Algorithm converged.	0,53	2,04
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	11	6	205	15,4	32	15,6	0,35	Algorithm converged.	0,17	0,71	-9,599	Algorithm converged.	-15,64	-3,55	0,39	Algorithm converged.	0,2	0,74	0,0027		2,6	Algorithm converged.	1,35	5
	>10 ⁷ copies/mL	590	44,4	62	10,5	561	42,1	63	11,2	0,93	Algorithm converged.	0,64	1,35	-0,721	Algorithm converged.	-4,32	2,88	0,94	Algorithm converged.	0,67	1,3	0,6943		1,07	Algorithm converged.	0,77	1,49
	Unknown	29	2,2	1	3,4	23	1,7	1	4,3	0,79	Algorithm converged.	0,05	13,28	-0,9	Algorithm converged.	-11,56	9,76	0,79	Algorithm converged.	0,05	12,01	1		1,26	Algorithm converged.	0,08	19,09
Country	USA	1237	93,1	118	9,5	1239	93	134	10,8	0,87	Algorithm converged.	0,67	1,13	-1,276	Algorithm converged.	-3,66	1,11	0,88	Algorithm converged.	0,7	1,12	0,2938	0,4156	1,13	Algorithm converged.	0,9	1,43
	MEX	92	6,9	3	3,3	93	7	6	6,5	0,49	Algorithm converged.	0,12	2,02	-3,191	Algorithm converged.	-9,36	2,98	0,51	Algorithm converged.	0,13	1,96	0,4969		1,98	Algorithm converged.	0,51	7,67

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-2-ae-raw-anyaenr

POPULATION: Safety
 ENDPOINT: AEs grade >= 3
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk		Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	24	1,8	1332	100	49	3,7	0,48	Algorithm converged.	0,29	0,79	-1,873	Algorithm converged.	-3,11	-0,63	0,49	Algorithm converged.	0,3	0,8	0,0031		2,04	Algorithm converged.	1,26	3,3
Sex	Male	641	48,2	14	2,2	634	47,6	24	3,8	0,57	Algorithm converged.	0,29	1,11	-1,601	Algorithm converged.	-3,47	0,27	0,58	Algorithm converged.	0,3	1,11	0,0928	0,4773	1,73	Algorithm converged.	0,9	3,32
	Female	688	51,8	10	1,5	698	52,4	25	3,6	0,4	Algorithm converged.	0,19	0,83	-2,128	Algorithm converged.	-3,77	-0,48	0,41	Algorithm converged.	0,2	0,84	0,0116		2,46	Algorithm converged.	1,19	5,09
Age	18-64	1168	87,9	16	1,4	1183	88,8	30	2,5	0,53	Algorithm converged.	0,29	0,98	-1,166	Algorithm converged.	-2,28	-0,05	0,54	Algorithm converged.	0,3	0,99	0,0413	0,7155	1,85	Algorithm converged.	1,01	3,38
	65-74	110	8,3	4	3,6	114	8,6	11	9,6	0,35	Algorithm converged.	0,11	1,15	-6,013	Algorithm converged.	-12,46	0,44	0,38	Algorithm converged.	0,12	1,15	0,107		2,65	Algorithm converged.	0,87	8,08
	>=75	51	3,8	4	7,8	35	2,6	8	22,9	0,29	Algorithm converged.	0,08	1,04	-15,014	Algorithm converged.	-30,76	0,73	0,34	Algorithm converged.	0,11	1,05	0,0617		2,91	Algorithm converged.	0,95	8,94
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	5	1,4	360	27	4	1,1	1,22	Algorithm converged.	0,32	4,58	0,24	Algorithm converged.	-1,36	1,84	1,22	Algorithm converged.	0,33	4,49	1	0,2218	0,82	Algorithm converged.	0,22	3,04
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	2	1,3	183	13,7	4	2,2	0,58	Algorithm converged.	0,1	3,2	-0,912	Algorithm converged.	-3,66	1,84	0,58	Algorithm converged.	0,11	3,14	0,6903		1,72	Algorithm converged.	0,32	9,24
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	2	1,1	205	15,4	13	6,3	0,16	Algorithm converged.	0,04	0,73	-5,249	Algorithm converged.	-8,91	-1,59	0,17	Algorithm converged.	0,04	0,75	0,0076		5,8	Algorithm converged.	1,33	25,37
	>10 ⁷ copies/mL	590	44,4	15	2,5	561	42,1	28	5	0,5	Algorithm converged.	0,26	0,94	-2,449	Algorithm converged.	-4,65	-0,24	0,51	Algorithm converged.	0,28	0,94	0,0286		1,96	Algorithm converged.	1,06	3,64
	Unknown	29	2,2	0	0	23	1,7	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	22	1,8	1239	93	43	3,5	0,5	Algorithm converged.	0,3	0,85	-1,692	Algorithm converged.	-2,95	-0,43	0,51	Algorithm converged.	0,31	0,85	0,0085	0,6093	1,95	Algorithm converged.	1,17	3,24
	MEX	92	6,9	2	2,2	93	7	6	6,5	0,32	Algorithm converged.	0,06	1,64	-4,278	Algorithm converged.	-10,09	1,54	0,34	Algorithm converged.	0,07	1,63	0,2783		2,97	Algorithm converged.	0,61	14,32

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-3-ae-raw-toxrgt3

POPULATION: Safety
 ENDPOINT: AEs Grade >= 3 (excluding disease related events)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk				
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	20	1,5	1332	100	39	2,9	0,51	Algorithm converged.	0,29	0,87	-1,423	Algorithm converged.	-2,54	-0,31	0,51	Algorithm converged.	0,3	0,88	0,0127		1,95	Algorithm converged.	1,14	3,32
Sex	Male	641	48,2	10	1,6	634	47,6	18	2,8	0,54	Algorithm converged.	0,25	1,18	-1,279	Algorithm converged.	-2,89	0,33	0,55	Algorithm converged.	0,26	1,18	0,1193	0,8133	1,82	Algorithm converged.	0,85	3,91
	Female	688	51,8	10	1,5	698	52,4	21	3	0,48	Algorithm converged.	0,22	1,02	-1,555	Algorithm converged.	-3,11	0	0,48	Algorithm converged.	0,23	1,02	0,0504		2,07	Algorithm converged.	0,98	4,36
Age	18-64	1168	87,9	14	1,2	1183	88,8	24	2	0,59	Algorithm converged.	0,3	1,14	-0,83	Algorithm converged.	-1,85	0,19	0,59	Algorithm converged.	0,31	1,14	0,1106	0,4852	1,69	Algorithm converged.	0,88	3,26
	65-74	110	8,3	2	1,8	114	8,6	9	7,9	0,22	Algorithm converged.	0,05	1,02	-6,077	Algorithm converged.	-11,62	-0,53	0,23	Algorithm converged.	0,05	1,04	0,0594		4,34	Algorithm converged.	0,96	19,65
	>=75	51	3,8	4	7,8	35	2,6	6	17,1	0,41	Algorithm converged.	0,11	1,58	-9,3	Algorithm converged.	-23,8	5,2	0,46	Algorithm converged.	0,14	1,5	0,3043		2,19	Algorithm converged.	0,67	7,18
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	5	1,4	360	27	3	0,8	1,63	Algorithm converged.	0,39	6,87	0,518	Algorithm converged.	-0,99	2,02	1,62	Algorithm converged.	0,39	6,74	0,7253	0,2283	0,62	Algorithm converged.	0,15	2,56
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	2	1,3	183	13,7	3	1,6	0,77	Algorithm converged.	0,13	4,69	-0,365	Algorithm converged.	-2,91	2,18	0,78	Algorithm converged.	0,13	4,59	1		1,29	Algorithm converged.	0,22	7,6
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	2	1,1	205	15,4	10	4,9	0,22	Algorithm converged.	0,05	1	-3,785	Algorithm converged.	-7,1	-0,47	0,22	Algorithm converged.	0,05	1,01	0,0393		4,46	Algorithm converged.	0,99	20,1
	>10 ⁷ copies/mL	590	44,4	11	1,9	561	42,1	23	4,1	0,44	Algorithm converged.	0,21	0,92	-2,235	Algorithm converged.	-4,21	-0,26	0,45	Algorithm converged.	0,22	0,92	0,0252		2,2	Algorithm converged.	1,08	4,47
	Unknown	29	2,2	0	0	23	1,7	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	20	1,6	1239	93	37	3	0,53	Algorithm converged.	0,31	0,93	-1,369	Algorithm converged.	-2,55	-0,19	0,54	Algorithm converged.	0,32	0,93	0,0231	0,1936	1,85	Algorithm converged.	1,08	3,16
	MEX	92	6,9	0	0	93	7	2	2,2	0	Algorithm converged.	NE	NE	-2,151	Algorithm converged.	-5,1	0,8	NE *	Algorithm not converged.	NE	NE	0,4973		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-4-ae-raw-toxinr3

POPULATION: Safety
 ENDPOINT: AEs grade 3
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	21	1.6	1332	100	39	2.9	0.53	Algorithm converged.	0.31	0.91	-1.348	Algorithm converged.	-2.47	-0.22	0.54	Algorithm converged.	0.32	0.91	0.0192		1.85	Algorithm converged.	1.1	3.13
Sex	Male	641	48.2	12	1.9	634	47.6	21	3.3	0.56	Algorithm converged.	0.27	1.14	-1.44	Algorithm converged.	-3.18	0.3	0.57	Algorithm converged.	0.28	1.14	0.1055	0.8412	1.77	Algorithm converged.	0.88	3.57
	Female	688	51.8	9	1.3	698	52.4	18	2.6	0.5	Algorithm converged.	0.22	1.12	-1.271	Algorithm converged.	-2.72	0.18	0.51	Algorithm converged.	0.23	1.12	0.0871		1.97	Algorithm converged.	0.89	4.36
Age	18-64	1168	87.9	13	1.1	1183	88.8	26	2.2	0.5	Algorithm converged.	0.26	0.98	-1.085	Algorithm converged.	-2.11	-0.06	0.51	Algorithm converged.	0.26	0.98	0.0395	0.6802	1.97	Algorithm converged.	1.02	3.82
	65-74	110	8.3	4	3.6	114	8.6	10	8.8	0.39	Algorithm converged.	0.12	1.29	-5.136	Algorithm converged.	-11.4	1.13	0.41	Algorithm converged.	0.13	1.28	0.1667		2.41	Algorithm converged.	0.78	7.46
	>=75	51	3.8	4	7.8	35	2.6	3	8.6	0.91	Algorithm converged.	0.19	4.33	-0.728	Algorithm converged.	-12.58	11.12	0.92	Algorithm converged.	0.22	3.84	1		1.09	Algorithm converged.	0.26	4.58
Baseline viral load categories	<=10^5 copies/mL	370	27.8	4	1.1	360	27	4	1.1	0.97	Algorithm converged.	0.24	3.92	-0.03	Algorithm converged.	-1.54	1.48	0.97	Algorithm converged.	0.25	3.86	1	0.2174	1.03	Algorithm converged.	0.26	4.08
	>10^5 copies/mL - <=10^6 copies/mL	157	11.8	2	1.3	183	13.7	3	1.6	0.77	Algorithm converged.	0.13	4.69	-0.365	Algorithm converged.	-2.91	2.18	0.78	Algorithm converged.	0.13	4.59	1		1.29	Algorithm converged.	0.22	7.6
	>10^6 copies/mL - <=10^7 copies/mL	183	13.8	1	0.5	205	15.4	10	4.9	0.11	Algorithm converged.	0.01	0.85	-4.332	Algorithm converged.	-7.47	-1.2	0.11	Algorithm converged.	0.01	0.87	0.012		8.93	Algorithm converged.	1.15	69.06
	>10^7 copies/mL	590	44.4	14	2.4	561	42.1	22	3.9	0.6	Algorithm converged.	0.3	1.18	-1.549	Algorithm converged.	-3.57	0.47	0.61	Algorithm converged.	0.31	1.17	0.1315		1.65	Algorithm converged.	0.85	3.2
	Unknown	29	2.2	0	0	23	1.7	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1237	93.1	19	1.5	1239	93	36	2.9	0.52	Algorithm converged.	0.3	0.91	-1.37	Algorithm converged.	-2.53	-0.21	0.53	Algorithm converged.	0.3	0.92	0.0208	0.7985	1.89	Algorithm converged.	1.09	3.28
	MEX	92	6.9	2	2.2	93	7	3	3.2	0.67	Algorithm converged.	0.11	4.09	-1.052	Algorithm converged.	-5.72	3.61	0.67	Algorithm converged.	0.12	3.94	1		1.48	Algorithm converged.	0.25	8.68

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * Indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-5-ae-raw-toxg3

POPULATION: Safety
 ENDPOINT: AEs grade 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference		Relative Risk			Interaction Test		Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	2	0,2	1332	100	3	0,2	0,67	Algorithm converged.	0,11	4	-0,075	Algorithm converged.	-0,4	0,25	0,67	Algorithm converged.	0,11	3,99	1		1,5	Algorithm converged.	0,25	8,94
Sex	Male	641	48,2	1	0,2	634	47,6	1	0,2	0,99	Algorithm converged.	0,06	15,85	-0,002	Algorithm converged.	-0,44	0,43	0,99	Algorithm converged.	0,06	15,78	1	0,7198	1,01	Algorithm converged.	0,06	16,13
	Female	688	51,8	1	0,1	698	52,4	2	0,3	0,51	Algorithm converged.	0,05	5,6	-0,141	Algorithm converged.	-0,63	0,35	0,51	Algorithm converged.	0,05	5,58	1		1,97	Algorithm converged.	0,18	21,69
Age	18-64	1168	87,9	2	0,2	1183	88,8	3	0,3	0,67	Algorithm converged.	0,11	4,05	-0,082	Algorithm converged.	-0,45	0,29	0,68	Algorithm converged.	0,11	4,03	1		1,48	Algorithm converged.	0,25	8,85
	65-74	110	8,3	0	0	114	8,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
	>=75	51	3,8	0	0	35	2,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	0	0	360	27	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	0,7773	NE *	Algorithm not converged.	NE	NE
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	0	0	183	13,7	1	0,5	0	Algorithm converged.	NE	NE	-0,546	Algorithm converged.	-1,61	0,52	NE	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	1	0,5	205	15,4	1	0,5	1,12	Algorithm converged.	0,07	18,05	0,059	Algorithm converged.	-1,37	1,49	1,12	Algorithm converged.	0,07	17,78	1		0,89	Algorithm converged.	0,06	14,17
	>10 ⁷ copies/mL	590	44,4	1	0,2	561	42,1	1	0,2	0,95	Algorithm converged.	0,06	15,24	-0,009	Algorithm converged.	-0,49	0,47	0,95	Algorithm converged.	0,06	15,17	1		1,05	Algorithm converged.	0,07	16,77
	Unknown	29	2,2	0	0	23	1,7	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	2	0,2	1239	93	2	0,2	1	Algorithm converged.	0,14	7,12	0	Algorithm converged.	-0,32	0,32	1	Algorithm converged.	0,14	7,1	1	0,2771	1	Algorithm converged.	0,14	7,06
	MEX	92	6,9	0	0	93	7	1	1,1	0	Algorithm converged.	NE	NE	-1,075	Algorithm converged.	-3,17	1,02	NE	Algorithm not converged.	NE	NE	1		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-6-ae-raw-toxgr4

POPULATION: Safety
 ENDPOINT: AEs grade 5 (AEs leading to death)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Odds Ratio			Absolute Risk Difference			Casirivimab/Imdevimab vs. Placebo				Relative Risk			Placebo vs. Casirivimab/Imdevimab				
		Patients		Event		Patients		Event		Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		n	%	n	%	n	%	n	%																		
All	n/a	1329	100	1	0,1	1332	100	7	0,5	0,14	Algorithm converged.	0,02	1,16	-0,45	Algorithm converged.	-0,87	-0,03	0,14	Algorithm converged.	0,02	1,16	0,0699		6,98	Algorithm converged.	0,86	56,69
Sex	Male	641	48,2	1	0,2	634	47,6	2	0,3	0,49	Algorithm converged.	0,04	5,46	-0,159	Algorithm converged.	-0,69	0,37	0,49	Algorithm converged.	0,04	5,44	0,6227	0,1398	2,02	Algorithm converged.	0,18	22,24
	Female	688	51,8	0	0	698	52,4	5	0,7	0	Algorithm converged.	NE	NE	-0,716	Algorithm converged.	-1,34	-0,09	NE	Algorithm not converged.	NE	NE	0,0621		NE	Algorithm not converged.	NE	NE
Age	18-64	1168	87,9	1	0,1	1183	88,8	1	0,1	1,01	Algorithm converged.	0,06	16,21	0,001	Algorithm converged.	-0,23	0,24	1,01	Algorithm converged.	0,06	16,17	1		0,99	Algorithm converged.	0,06	15,77
	65-74	110	8,3	0	0	114	8,6	1	0,9	0	Algorithm converged.	NE	NE	-0,877	Algorithm converged.	-2,59	0,83	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	>=75	51	3,8	0	0	35	2,6	5	14,3	0	Algorithm converged.	NE	NE	-14,286	Algorithm converged.	-25,88	-2,69	NE	Algorithm not converged.	NE	NE	0,0093		NE	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10^5 copies/mL	370	27,8	1	0,3	360	27	0	0	NE	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,8	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	>10^5 copies/mL - <=10^6 copies/mL	157	11,8	0	0	183	13,7	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	>10^6 copies/mL - <=10^7 copies/mL	183	13,8	0	0	205	15,4	2	1	0	Algorithm converged.	NE	NE	-0,976	Algorithm converged.	-2,32	0,37	NE	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
	>10^7 copies/mL	590	44,4	0	0	561	42,1	5	0,9	0	Algorithm converged.	NE	NE	-0,891	Algorithm converged.	-1,67	-0,11	NE	Algorithm not converged.	NE	NE	0,0273		NE	Algorithm not converged.	NE	NE
	Unknown	29	2,2	0	0	23	1,7	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	1	0,1	1239	93	5	0,4	0,2	Algorithm converged.	0,02	1,71	-0,323	Algorithm converged.	-0,71	0,06	0,2	Algorithm converged.	0,02	1,71	0,2182	0,4316	4,99	Algorithm converged.	0,58	42,67
	MEX	92	6,9	0	0	93	7	2	2,2	0	Algorithm converged.	NE	NE	-2,151	Algorithm converged.	-5,1	0,8	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-7-ae-raw-toxgr5

POPULATION: Safety
 ENDPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	22	1,7	1332	100	56	4,2	0,38	Algorithm converged.	0,23	0,63	-2,549	Algorithm converged.	-3,83	-1,27	0,39	Algorithm converged.	0,24	0,64	<0,0001		2,54	Algorithm converged.	1,56	4,13
Sex	Male	641	48,2	12	1,9	634	47,6	27	4,3	0,43	Algorithm converged.	0,22	0,85	-2,387	Algorithm converged.	-4,28	-0,5	0,44	Algorithm converged.	0,22	0,86	0,0134	0,6466	2,27	Algorithm converged.	1,16	4,45
	Female	688	51,8	10	1,5	698	52,4	29	4,2	0,34	Algorithm converged.	0,16	0,7	-2,701	Algorithm converged.	-4,43	-0,97	0,35	Algorithm converged.	0,17	0,71	0,0024		2,86	Algorithm converged.	1,4	5,82
Age	18-64	1168	87,9	15	1,3	1183	88,8	34	2,9	0,44	Algorithm converged.	0,24	0,81	-1,59	Algorithm converged.	-2,74	-0,44	0,45	Algorithm converged.	0,24	0,82	0,007	0,5991	2,24	Algorithm converged.	1,23	4,09
	65-74	110	8,3	3	2,7	114	8,6	13	11,4	0,22	Algorithm converged.	0,06	0,79	-8,676	Algorithm converged.	-15,26	-2,1	0,24	Algorithm converged.	0,07	0,82	0,0173		4,18	Algorithm converged.	1,22	14,27
	>=75	51	3,8	4	7,8	35	2,6	9	25,7	0,25	Algorithm converged.	0,07	0,88	-17,871	Algorithm converged.	-34,12	-1,62	0,31	Algorithm converged.	0,1	0,91	0,0323		3,28	Algorithm converged.	1,1	9,81
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	5	1,4	360	27	8	2,2	0,6	Algorithm converged.	0,2	1,86	-0,871	Algorithm converged.	-2,8	1,05	0,61	Algorithm converged.	0,2	1,84	0,414	0,5329	1,64	Algorithm converged.	0,54	4,98
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	1	0,6	183	13,7	4	2,2	0,29	Algorithm converged.	0,03	2,59	-1,549	Algorithm converged.	-4,01	0,91	0,29	Algorithm converged.	0,03	2,58	0,3787		3,43	Algorithm converged.	0,39	30,39
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	2	1,1	205	15,4	13	6,3	0,16	Algorithm converged.	0,04	0,73	-5,249	Algorithm converged.	-8,91	-1,59	0,17	Algorithm converged.	0,04	0,75	0,0076		5,8	Algorithm converged.	1,33	25,37
	>10 ⁷ copies/mL	590	44,4	14	2,4	561	42,1	31	5,5	0,42	Algorithm converged.	0,22	0,79	-3,153	Algorithm converged.	-5,41	-0,9	0,43	Algorithm converged.	0,23	0,8	0,0058		2,33	Algorithm converged.	1,25	4,33
	Unknown	29	2,2	0	0	23	1,7	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	20	1,6	1239	93	49	4	0,4	Algorithm converged.	0,24	0,68	-2,338	Algorithm converged.	-3,63	-1,05	0,41	Algorithm converged.	0,24	0,68	0,0004	0,6676	2,45	Algorithm converged.	1,46	4,09
	MEX	92	6,9	2	2,2	93	7	7	7,5	0,27	Algorithm converged.	0,06	1,35	-5,353	Algorithm converged.	-11,49	0,78	0,29	Algorithm converged.	0,06	1,35	0,169		3,46	Algorithm converged.	0,74	16,23

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-8-ae-raw-anyxae

POPULATION: Safety
 ENDPOINT: Any SAEs (excluding disease related events)
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab		Placebo		Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
		Patients		Event		Patients		Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	17	1.3	1332	100	42	3.2	0.4	Algorithm converged.	0.23	0.7	-1.874	Algorithm converged.	-2.99	-0.76	0.41	Algorithm converged.	0.23	0.71	0.001		2.47	Algorithm converged.	1.41	4.31
Sex	Male	641	48.2	8	1.2	634	47.6	19	3	0.41	Algorithm converged.	0.18	0.94	-1.749	Algorithm converged.	-3.33	-0.17	0.42	Algorithm converged.	0.18	0.94	0.0302	0.9332	2.4	Algorithm converged.	1.06	5.45
	Female	688	51.8	9	1.3	698	52.4	23	3.3	0.39	Algorithm converged.	0.18	0.85	-1.987	Algorithm converged.	-3.56	-0.41	0.4	Algorithm converged.	0.19	0.85	0.0138		2.52	Algorithm converged.	1.17	5.4
Age	18-64	1168	87.9	13	1.1	1183	88.8	28	2.4	0.46	Algorithm converged.	0.24	0.9	-1.254	Algorithm converged.	-2.31	-0.2	0.47	Algorithm converged.	0.24	0.9	0.0203	0.4052	2.13	Algorithm converged.	1.11	4.08
	65-74	110	8.3	1	0.9	114	8.6	8	7	0.12	Algorithm converged.	0.01	0.99	-6.108	Algorithm converged.	-11.12	-1.1	0.13	Algorithm converged.	0.02	1.02	0.0356		7.72	Algorithm converged.	0.98	60.7
	>=75	51	3.8	3	5.9	35	2.6	6	17.1	0.3	Algorithm converged.	0.07	1.3	-11.261	Algorithm converged.	-25.32	2.8	0.34	Algorithm converged.	0.09	1.28	0.15		2.91	Algorithm converged.	0.78	10.88
Baseline viral load categories	<=10 ⁵ copies/mL	370	27.8	5	1.4	360	27	6	1.7	0.81	Algorithm converged.	0.24	2.67	-0.315	Algorithm converged.	-2.09	1.45	0.81	Algorithm converged.	0.25	2.63	0.7699	0.6087	1.23	Algorithm converged.	0.38	4.01
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11.8	1	0.6	183	13.7	3	1.6	0.38	Algorithm converged.	0.04	3.74	-1.002	Algorithm converged.	-3.22	1.22	0.39	Algorithm converged.	0.04	3.7	0.6272		2.57	Algorithm converged.	0.27	24.5
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13.8	2	1.1	205	15.4	9	4.4	0.24	Algorithm converged.	0.05	1.13	-3.297	Algorithm converged.	-6.48	-0.11	0.25	Algorithm converged.	0.05	1.14	0.0663		4.02	Algorithm converged.	0.88	18.35
	>10 ⁷ copies/mL	590	44.4	9	1.5	561	42.1	24	4.3	0.35	Algorithm converged.	0.16	0.75	-2.753	Algorithm converged.	-4.7	-0.81	0.36	Algorithm converged.	0.17	0.76	0.0052		2.8	Algorithm converged.	1.32	5.98
	Unknown	29	2.2	0	0	23	1.7	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE *	Algorithm not converged.	NE	NE
Country	USA	1237	93.1	17	1.4	1239	93	40	3.2	0.42	Algorithm converged.	0.24	0.74	-1.854	Algorithm converged.	-3.03	-0.68	0.43	Algorithm converged.	0.24	0.75	0.0021	0.2393	2.35	Algorithm converged.	1.34	4.12
	MEX	92	6.9	0	0	93	7	2	2.2	0	Algorithm converged.	NE	NE	-2.151	Algorithm converged.	-5.1	0.8	NE *	Algorithm not converged.	NE	NE	0.4973		NE *	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-9-ae-raw-any.sas

POPULATION: Safety
 ENDPOINT: AEs leading to treatment discontinuation
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
		Patients		Event		Patients		Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1329	100	1	0,1	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,07	0,22	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	*	Algorithm not converged.	NE	NE
Sex	Male	641	48,2	1	0,2	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,46	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Female	688	51,8	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Age	18-64	1168	87,9	1	0,1	1183	88,8	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,08	0,25	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	*	Algorithm not converged.	NE	NE
	65-74	110	8,3	0	0	114	8,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>=75	51	3,8	0	0	35	2,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	0	0	360	27	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	0	0	183	13,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	0	0	205	15,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁷ copies/mL	590	44,4	1	0,2	561	42,1	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,5	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Unknown	29	2,2	0	0	23	1,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	1	0,1	1239	93	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,24	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	*	Algorithm not converged.	NE	NE
	MEX	92	6,9	0	0	93	7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-10-ae-raw-aeltids

Datenschnitt 19.08.2021 (DCO2)

Verträglichkeit

AESI

POPULATION: Safety
 ENDPOINT: IRRs through day 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1329	100	1	0,1	1332	100	1	0,1	1	Algorithm converged.	0,06	16,04	0	Algorithm converged.	-0,21	0,21	1	Algorithm converged.	0,06	16,01	1		1	Algorithm converged.	0,06	15,93			
Sex	Male	641	48,2	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
	Female	688	51,8	1	0,1	698	52,4	1	0,1	1,01	Algorithm converged.	0,06	16,25	0,002	Algorithm converged.	-0,4	0,4	1,01	Algorithm converged.	0,06	16,19	1	0,99	*	Algorithm converged.	0,06	15,73			
Age	18-64	1168	87,9	1	0,1	1183	88,8	1	0,1	1,01	Algorithm converged.	0,06	16,21	0,001	Algorithm converged.	-0,23	0,24	1,01	Algorithm converged.	0,06	16,17	1	0,99	*	Algorithm converged.	0,06	15,77			
	65-74	110	8,3	0	0	114	8,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
	>=75	51	3,8	0	0	35	2,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
Baseline viral load categories	<=10^5 copies/mL	370	27,8	0	0	360	27	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
	>10^5 copies/mL - <=10^6 copies/mL	157	11,8	0	0	183	13,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
	>10^6 copies/mL - <=10^7 copies/mL	183	13,8	0	0	205	15,4	1	0,5	0	Algorithm converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,47	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE	
	>10^7 copies/mL	590	44,4	0	0	561	42,1	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
	Unknown	29	2,2	1	3,4	23	1,7	0	0	NE	*	Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,19	10,09	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	1	0,1	1239	93	1	0,1	1	Algorithm converged.	0,06	16,03	0	Algorithm converged.	-0,22	0,22	1	Algorithm converged.	0,06	16	1	1	1	Algorithm converged.	0,06	15,94			
	MEX	92	6,9	0	0	93	7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: 118-11-ae-raw-irr

POPULATION: Safety
 ENDPOINT: Grade >= 3 IRRs through day 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	n/a	1329	100	0	0	1332	100	0	0																			
Sex	Male	641	48,2	0	0	634	47,6	0	0																			
	Female	688	51,8	0	0	698	52,4	0	0																			
Age	18-64	1168	87,9	0	0	1183	88,8	0	0																			
	65-74	110	8,3	0	0	114	8,6	0	0																			
	>=75	51	3,8	0	0	35	2,6	0	0																			
Baseline viral load categories	<=10^5 copies/mL	370	27,8	0	0	360	27	0	0																			
	>10^5 copies/mL - <=10^6 copies/mL	157	11,8	0	0	183	13,7	0	0																			
	>10^6 copies/mL - <=10^7 copies/mL	183	13,8	0	0	205	15,4	0	0																			
	>10^7 copies/mL	590	44,4	0	0	561	42,1	0	0																			
	Unknown	29	2,2	0	0	23	1,7	0	0																			
Country	USA	1237	93,1	0	0	1239	93	0	0																			
	MEX	92	6,9	0	0	93	7	0	0																			

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-12-ae-raw-irge3

POPULATION: Safety
 ENDPOINT: Serious IRRs through day 4
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference			Relative Risk		Relative Risk			Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1329	100	0	0	1332	100	0	0																				
Sex	Male	641	48,2	0	0	634	47,6	0	0																				
	Female	688	51,8	0	0	698	52,4	0	0																				
Age	18-64	1168	87,9	0	0	1183	88,8	0	0																				
	65-74	110	8,3	0	0	114	8,6	0	0																				
	>=75	51	3,8	0	0	35	2,6	0	0																				
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	0	0	360	27	0	0																				
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	0	0	183	13,7	0	0																				
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	0	0	205	15,4	0	0																				
	>10 ⁷ copies/mL	590	44,4	0	0	561	42,1	0	0																				
	Unknown	29	2,2	0	0	23	1,7	0	0																				
Country	USA	1237	93,1	0	0	1239	93	0	0																				
	MEX	92	6,9	0	0	93	7	0	0																				

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-13-ae-raw-sirr

POPULATION: Safety
 ENDPOINT: Hypersensitivity through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk												
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	n/a	1329	100	1	0,1	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,07	0,22	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	*	Algorithm not converged.	NE	NE
Sex	Male	641	48,2	1	0,2	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,46	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Female	688	51,8	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Age	18-64	1168	87,9	0	0	1183	88,8	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	65-74	110	8,3	1	0,9	114	8,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,86	2,68	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	*	Algorithm not converged.	NE	NE
	>=75	51	3,8	0	0	35	2,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	0	0	360	27	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	0	0	183	13,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	0	0	205	15,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
	>10 ⁷ copies/mL	590	44,4	1	0,2	561	42,1	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,5	NE	*	Algorithm not converged.	NE	NE	1		NE	*	Algorithm not converged.	NE	NE
	Unknown	29	2,2	0	0	23	1,7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE
Country	USA	1237	93,1	1	0,1	1239	93	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,24	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	*	Algorithm not converged.	NE	NE
	MEX	92	6,9	0	0	93	7	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	*	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-14-ae-raw-hyp

POPULATION: Safety
 ENDPOINT: Grade >= 3 Hypersensitivity through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	n/a	1329	100	0	0	1332	100	0	0																				
Sex	Male	641	48,2	0	0	634	47,6	0	0																				
	Female	688	51,8	0	0	698	52,4	0	0																				
Age	18-64	1168	87,9	0	0	1183	88,8	0	0																				
	65-74	110	8,3	0	0	114	8,6	0	0																				
	>=75	51	3,8	0	0	35	2,6	0	0																				
Baseline viral load categories	<=10^5 copies/mL	370	27,8	0	0	360	27	0	0																				
	>10^5 copies/mL - <=10^6 copies/mL	157	11,8	0	0	183	13,7	0	0																				
	>10^6 copies/mL - <=10^7 copies/mL	183	13,8	0	0	205	15,4	0	0																				
	>10^7 copies/mL	590	44,4	0	0	561	42,1	0	0																				
	Unknown	29	2,2	0	0	23	1,7	0	0																				
Country	USA	1237	93,1	0	0	1239	93	0	0																				
	MEX	92	6,9	0	0	93	7	0	0																				

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-15-ae-raw-hypge3

POPULATION: Safety
 ENDPOINT: Serious Hypersensitivity through day 29
 MODEL: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
		Patients		Event		Patients		Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk									
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	n/a	1329	100	0	0	1332	100	0	0																		
Sex	Male	641	48,2	0	0	634	47,6	0	0																		
	Female	688	51,8	0	0	698	52,4	0	0																		
Age	18-64	1168	87,9	0	0	1183	88,8	0	0																		
	65-74	110	8,3	0	0	114	8,6	0	0																		
	>=75	51	3,8	0	0	35	2,6	0	0																		
Baseline viral load categories	<=10 ⁵ copies/mL	370	27,8	0	0	360	27	0	0																		
	>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,8	0	0	183	13,7	0	0																		
	>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,8	0	0	205	15,4	0	0																		
	>10 ⁷ copies/mL	590	44,4	0	0	561	42,1	0	0																		
	Unknown	29	2,2	0	0	23	1,7	0	0																		
Country	USA	1237	93,1	0	0	1239	93	0	0																		
	MEX	92	6,9	0	0	93	7	0	0																		

Test for interaction based on RR (Log-binomial regression).
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 19Aug2021

Program: t-ae-raw.sas, binary1-excel18.sas
 Output: t18-16-ae-raw-shyp

Datenschnitt 19.08.2021 (DCO2)

Verträglichkeit

SOC-PT

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	Blood and lymphatic system disorders	--	--	1329	100	6	0,451	1332	100	2	0,15	3,016	Algorithm converged.	0,608	14,969	0,301	Algorithm converged.	-0,115	0,717	3,007	Algorithm converged.	0,608	14,87	0,1786		0,333	Algorithm converged.	0,067	1,645		
	Eosinophilia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Iron deficiency anaemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Leukocytosis	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Leukopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Lymphopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Thrombocytopenia	--	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE	*	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE	
	Thrombocytosis	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495		
	Cardiac disorders	--	--	1329	100	4	0,301	1332	100	6	0,45	0,667	Algorithm converged.	0,188	2,37	-0,149	Algorithm converged.	-0,614	0,315	0,668	Algorithm converged.	0,189	2,362	0,7534		1,497	Algorithm converged.	0,423	5,291		
	Acute myocardial infarction	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Angina pectoris	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Arrhythmia neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Atrial fibrillation	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98		
	Cardiac failure congestive	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Coronary artery disease	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Palpitations	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935		
	Sinus tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Tachycardia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Eye disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cataract	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	9	0,677	1332	100	15	1,126	0,599	Algorithm converged.	0,261	1,373	-0,449	Algorithm converged.	-1,167	0,269	0,601		Algorithm converged.	0,264	1,369	0,2208		1,663	Algorithm converged.	0,73	3,787
		Abdominal distension	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Abdominal pain	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Abdominal pain upper	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Chronic gastritis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Constipation	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Diarrhoea	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Gastric ulcer	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Gastritis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	--	1329	100	2	0,15	1332	100	2	0,15	1,002	Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002		Algorithm converged.	0,141	7,105	1		0,998	Algorithm converged.	0,141	7,073
		Nausea	--	1329	100	4	0,301	1332	100	4	0,3	1,002	Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002		Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
		Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vomiting	--	1329	100	0	0	1332	100	5	0,375	NE *	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE	*	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	General disorders and administration site conditions	--	--	1329	100	9	0,677	1332	100	19	1,426	0,471	Algorithm converged.	0,212	1,045	-0,749	Algorithm converged.	-1,524	0,025	0,475	Algorithm converged.	0,216	1,045	0,0583		2,106	Algorithm converged.	0,956	4,639
	Chest discomfort	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Death	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Fatigue	--	--	1329	100	2	0,15	1332	100	3	0,225	0,668	Algorithm converged.	0,111	4,002	-0,075	Algorithm converged.	-0,404	0,254	0,668	Algorithm converged.	0,112	3,992	1		1,497	Algorithm converged.	0,25	8,942
	Fever neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Multiple organ dysfunction syndrome	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Oedema peripheral	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Pain	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Peripheral swelling	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Pyrexia	--	--	1329	100	2	0,15	1332	100	6	0,45	0,333	Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334	Algorithm converged.	0,068	1,652	0,2883		2,993	Algorithm converged.	0,605	14,803
	Swelling face	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Cholecystitis acute	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hyperbilirubinaemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Immune system disorders	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Seasonal allergy	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	33	2,483	1332	100	64	4,805	0,504		Algorithm converged.	0,329	0,773	-2,322	Algorithm converged.	-3,743	-0,901	0,517		Algorithm converged.	0,342	0,781	0,0014		1,935	Algorithm converged.	1,28	2,925
	Bacteraemia	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Breast abscess	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Bronchitis	--	--	1329	100	4	0,301	1332	100	1	0,075	4,018		Algorithm converged.	0,449	35,997	0,226	Algorithm converged.	-0,103	0,555	4,009		Algorithm converged.	0,449	35,821	0,2179		0,249	Algorithm converged.	0,028	2,229
	COVID-19 pneumonia	--	--	1329	100	7	0,527	1332	100	27	2,027	0,256		Algorithm converged.	0,111	0,59	-1,5	Algorithm converged.	-2,351	-0,649	0,26		Algorithm converged.	0,114	0,595	0,0006		3,848	Algorithm converged.	1,682	8,806
	COVID-19 pneumonia	--	--	1329	100	5	0,376	1332	100	10	0,751	0,499		Algorithm converged.	0,17	1,465	-0,375	Algorithm converged.	-0,943	0,194	0,501		Algorithm converged.	0,172	1,462	0,3004		1,995	Algorithm converged.	0,684	5,822
	Cellulitis	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Clostridium difficile colitis	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastroenteritis	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Kidney infection	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Lung abscess	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Osteomyelitis acute	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pharyngitis streptococcal	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Pneumonia bacterial	--	--	1329	100	7	0,527	1332	100	14	1,051	0,498		Algorithm converged.	0,201	1,239	-0,524	Algorithm converged.	-1,196	0,148	0,501		Algorithm converged.	0,203	1,238	0,1265		1,995	Algorithm converged.	0,808	4,928
	Pneumonia bacterial	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Pneumonia viral	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Rectal abscess	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sinusitis	--	1329	100	4	0,301	1332	100	3	0,225	1,337	Algorithm converged.	0,299	5,987	0,076	Algorithm converged.	-0,314	0,465	1,336		Algorithm converged.	0,3	5,959	0,7259		0,748	Algorithm converged.	0,168	3,337
		Superinfection bacterial	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Tooth abscess	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper respiratory tract infection	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Urinary tract infection	--	1329	100	4	0,301	1332	100	1	0,075	4,018	Algorithm converged.	0,449	35,997	0,226	Algorithm converged.	-0,103	0,555	4,009		Algorithm converged.	0,449	35,821	0,2179		0,249	Algorithm converged.	0,028	2,229
		Injury, poisoning and procedural complications	--	1329	100	7	0,527	1332	100	1	0,075	7,048	Algorithm converged.	0,866	57,361	0,452	Algorithm converged.	0,036	0,868	7,016		Algorithm converged.	0,864	56,944	0,0386		0,143	Algorithm converged.	0,018	1,157
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Contusion	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE	*	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Infusion related reaction	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Ligament sprain	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Skin laceration	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Investigations	--	1329	100	26	1,956	1332	100	23	1,727	1,136			Algorithm converged.	0,645	2,001	0,23	Algorithm converged.	-0,792	1,251	1,133		Algorithm converged.	0,65	1,975	0,6596		0,883	Algorithm converged.	0,506	1,539
		Activated partial thromboplastin time prolonged	--	1329	100	7	0,527	1332	100	7	0,526	1,002		Algorithm converged.	0,351	2,865	0,001	Algorithm converged.	-0,549	0,551	1,002		Algorithm converged.	0,353	2,849	0,9966		0,998	Algorithm converged.	0,351	2,837
		Alanine aminotransferase increased	--	1329	100	4	0,301	1332	100	4	0,3	1,002		Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002		Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
		Aspartate aminotransferase increased	--	1329	100	2	0,15	1332	100	1	0,075	2,006		Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005		Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
		Bleeding time prolonged	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	--	1329	100	5	0,376	1332	100	2	0,15	2,511		Algorithm converged.	0,486	12,967	0,226	Algorithm converged.	-0,163	0,615	2,506		Algorithm converged.	0,487	12,892	0,288		0,399	Algorithm converged.	0,078	2,053
		Blood lactate dehydrogenase increased	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	--	1329	100	7	0,527	1332	100	7	0,526	1,002		Algorithm converged.	0,351	2,865	0,001	Algorithm converged.	-0,549	0,551	1,002		Algorithm converged.	0,353	2,849	0,9966		0,998	Algorithm converged.	0,351	2,837
		Fibrin D dimer increased	--	1329	100	7	0,527	1332	100	9	0,676	0,778		Algorithm converged.	0,289	2,096	-0,149	Algorithm converged.	-0,736	0,438	0,78		Algorithm converged.	0,291	2,087	0,6193		1,283	Algorithm converged.	0,479	3,434
		Heart rate decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	--	1329	100	2	0,15	1332	100	2	0,15	1,002		Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002		Algorithm converged.	0,141	7,105	1		0,998	Algorithm converged.	0,141	7,073

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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		International normalised ratio increased	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244			0,499	Algorithm converged.	0,045	5,495
		Prothrombin time prolonged	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244			0,499	Algorithm converged.	0,045	5,495
		Serum ferritin increased	--	1329	100	0	0	1332	100	3	0,225	NE *	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Transaminases increased	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	1329	100	9	0,677	1332	100	13	0,976	0,692	Algorithm converged.	0,295	1,624	-0,299	Algorithm converged.	-0,987	0,389	0,694	Algorithm converged.	0,298	1,618	0,3948			1,441	Algorithm converged.	0,618	3,36
		Dehydration	--	1329	100	0	0	1332	100	6	0,45	NE *	Algorithm not converged.	NE	NE	-0,45	Algorithm converged.	-0,81	-0,091	NE	*	Algorithm not converged.	NE	NE	0,0311		NE	Algorithm not converged.	NE	NE
		Haemochromatosis	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247			2,993	Algorithm converged.	0,312	28,739
		Hyperglycaemia	--	1329	100	3	0,226	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1			0,998	Algorithm converged.	0,062	15,935
		Hyponatraemia	--	1329	100	2	0,15	1332	100	3	0,225	0,668	Algorithm converged.	0,111	4,002	-0,075	Algorithm converged.	-0,404	0,254	0,668	Algorithm converged.	0,112	3,992	1			1,497	Algorithm converged.	0,25	8,942
		Malnutrition	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1			0,998	Algorithm converged.	0,062	15,935
	Musculoskeletal and connective tissue disorders	--	--	1329	100	4	0,301	1332	100	10	0,751	0,399	Algorithm converged.	0,125	1,276	-0,45	Algorithm converged.	-0,999	0,099	0,401	Algorithm converged.	0,126	1,275	0,1784			2,494	Algorithm converged.	0,784	7,933
		Arthralgia	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1			1,995	Algorithm converged.	0,181	21,98

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Arthritis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Back pain	--	1329	100	0	0	1332	100	3	0,225	NE *	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Costochondritis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Joint effusion	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Myalgia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pain in extremity	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Squamous cell carcinoma of skin	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Nervous system disorders	--	1329	100	12	0,903	1332	100	11	0,826	1,094	Algorithm converged.	0,481	2,489	0,077	Algorithm converged.	-0,626	0,781	1,093	Algorithm converged.	0,484	2,469	0,8299		0,915	Algorithm converged.	0,405	2,065
		Ageusia	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		Anosmia	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Bell's palsy	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Dementia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Dizziness	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	3	0,226	1332	100	4	0,3	0,751	Algorithm converged.	0,168	3,363	-0,075	Algorithm converged.	-0,464	0,315	0,752	Algorithm converged.	0,169	3,352	1		1,33	Algorithm converged.	0,298	5,932
		Hypogeusia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyposmia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Parosmia	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Presyncope	--	1329	100	0	0	1332	100	3	0,225	NE *	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tremor	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Pregnancy, puerperium and perinatal conditions	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Ectopic pregnancy	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Pregnancy	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Psychiatric disorders	--	1329	100	4	0,301	1332	100	3	0,225	1,337	Algorithm converged.	0,299	5,987	0,076	Algorithm converged.	-0,314	0,465	1,336	Algorithm converged.	0,3	5,959	0,7259		0,748	Algorithm converged.	0,168	3,337
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Insomnia	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Mental status changes	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
		Heavy menstrual bleeding	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Testicular pain	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	27	2,032	1332	100	41	3,078	0,653	Algorithm converged.	0,399	1,068	-1,046	Algorithm converged.	-2,245	0,152	0,66	Algorithm converged.	0,408	1,066	0,0872		1,515	Algorithm converged.	0,938	2,448
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Asthma	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Bronchial secretion retention	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Bronchospasm	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cough	--	1329	100	11	0,828	1332	100	8	0,601	1,381		Algorithm converged.	0,554	3,445	0,227	Algorithm converged.	-0,413	0,867	1,378		Algorithm converged.	0,556	3,415	0,4867	0,726		Algorithm converged.	0,293	1,798
		Dyspnoea	--	1329	100	8	0,602	1332	100	16	1,201	0,498		Algorithm converged.	0,212	1,168	-0,599	Algorithm converged.	-1,317	0,119	0,501		Algorithm converged.	0,215	1,167	0,1021	1,995		Algorithm converged.	0,857	4,647
		Dyspnoea exertional	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Epistaxis	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Hypoxia	--	1329	100	2	0,15	1332	100	6	0,45	0,333		Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334		Algorithm converged.	0,068	1,652	0,2883	2,993		Algorithm converged.	0,605	14,803
		Nasal congestion	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1	1,995		Algorithm converged.	0,181	21,98
		Oropharyngeal pain	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Productive cough	--	1329	100	2	0,15	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE	*	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Pulmonary congestion	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Respiratory distress	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Respiratory tract congestion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sinus congestion	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

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				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Skin and subcutaneous tissue disorders	--	--	--	1329	100	6	0,451	1332	100	6	0,45	1,002	Algorithm converged.	0,322	3,116	0,001	Algorithm converged.	-0,508	0,51	1,002	Algorithm converged.	0,324	3,1	0,9969		0,998	Algorithm converged.	0,323	3,086
	Acne	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pruritus	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Rash	--	--	1329	100	6	0,451	1332	100	4	0,3	1,506	Algorithm converged.	0,424	5,348	0,151	Algorithm converged.	-0,314	0,616	1,503	Algorithm converged.	0,425	5,315	0,5477		0,665	Algorithm converged.	0,188	2,352
Surgical and medical procedures	--	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hospitalisation	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Vascular disorders	--	--	--	1329	100	2	0,15	1332	100	5	0,375	0,4	Algorithm converged.	0,077	2,065	-0,225	Algorithm converged.	-0,614	0,164	0,401	Algorithm converged.	0,078	2,063	0,4525		2,494	Algorithm converged.	0,485	12,834
	Flushing	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Hypertension	--	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
	May-Thurner syndrome	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Thrombophlebitis superficial	--	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Blood and lymphatic system disorders	--	--	1329	100	6	0,451	1332	100	2	0,15	3,016	Algorithm converged.	0,608	14,969	0,301	Algorithm converged.	-0,115	0,717	3,007	Algorithm converged.	0,608	14,87	0,1786		0,333	Algorithm converged.	0,067	1,645
	Eosinophilia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Iron deficiency anaemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Leukocytosis	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Leukopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Lymphopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Thrombocytopenia	--	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
	Thrombocytosis	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
	Cardiac disorders	--	--	1329	100	4	0,301	1332	100	6	0,45	0,667	Algorithm converged.	0,188	2,37	-0,149	Algorithm converged.	-0,614	0,315	0,668	Algorithm converged.	0,189	2,362	0,7534		1,497	Algorithm converged.	0,423	5,291
	Acute myocardial infarction	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Angina pectoris	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Cardiac failure congestive	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Coronary artery disease	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Palpitations	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Sinus tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Eye disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm not converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cataract	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm not converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	9	0,677	1332	100	15	1,126	0,599		Algorithm converged.	0,261	1,373	-0,449	Algorithm converged.	-1,167	0,269	0,601		Algorithm converged.	0,264	1,369	0,2208		1,663	Algorithm converged.	0,73	3,787
	Abdominal distension	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Abdominal pain	--	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Abdominal pain upper	--	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Chronic gastritis	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Constipation	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Diarrhoea	--	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
	Gastric ulcer	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Gastritis	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastroesophageal reflux disease	--	--	1329	100	2	0,15	1332	100	2	0,15	1,002		Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002		Algorithm converged.	0,141	7,105	1		0,998	Algorithm converged.	0,141	7,073
	Nausea	--	--	1329	100	4	0,301	1332	100	4	0,3	1,002		Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002		Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
	Peptic ulcer perforation	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vomiting	--	--	1329	100	0	0	1332	100	5	0,375	NE	*	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE	*	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	9	0,677	1332	100	19	1,426	0,471		Algorithm converged.	0,212	1,045	-0,749	Algorithm converged.	-1,524	0,025	0,475		Algorithm converged.	0,216	1,045	0,0583		2,106	Algorithm converged.	0,956	4,639
	Chest discomfort	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Death	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Fatigue	--	1329	100	2	0,15	1332	100	3	0,225	0,668	Algorithm converged.	0,111	4,002	-0,075	Algorithm converged.	-0,404	0,254	0,668	Algorithm converged.	0,112	3,992	1		1,497	Algorithm converged.	0,25	8,942		
		Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE		
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98		
		Oedema peripheral	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE		
		Pain	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98		
		Peripheral swelling	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98		
		Pyrexia	--	1329	100	2	0,15	1332	100	6	0,45	0,333	Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334	Algorithm converged.	0,068	1,652	0,2883		2,993	Algorithm converged.	0,605	14,803		
		Swelling face	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935		
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE		
	Immune system disorders	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE		
		Seasonal allergy	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE		
	Infections and infestations	--	--	1329	100	33	2,483	1332	100	64	4,805	0,504	Algorithm converged.	0,329	0,773	-2,322	Algorithm converged.	-3,743	-0,901	0,517	Algorithm converged.	0,342	0,781	0,0014		1,935	Algorithm converged.	1,28	2,925		
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE		
		Breast abscess	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE		
		Bronchitis	--	1329	100	4	0,301	1332	100	1	0,075	4,018	Algorithm converged.	0,449	35,997	0,226	Algorithm converged.	-0,103	0,555	4,009	Algorithm converged.	0,449	35,821	0,2179		0,249	Algorithm converged.	0,028	2,229		

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		COVID-19	--	1329	100	7	0,527	1332	100	27	2,027	0,256	Algorithm converged.	0,111	0,59	-1,5	Algorithm converged.	-2,351	-0,649	0,26	Algorithm converged.	0,114	0,595	0,0006		3,848	Algorithm converged.	1,682	8,806
		COVID-19 pneumonia	--	1329	100	5	0,376	1332	100	10	0,751	0,499	Algorithm converged.	0,17	1,465	-0,375	Algorithm converged.	-0,943	0,194	0,501	Algorithm converged.	0,172	1,462	0,3004		1,995	Algorithm converged.	0,684	5,822
		Cellulitis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Kidney infection	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Pneumonia	--	1329	100	7	0,527	1332	100	14	1,051	0,498	Algorithm converged.	0,201	1,239	-0,524	Algorithm converged.	-1,196	0,148	0,501	Algorithm converged.	0,203	1,238	0,1265		1,995	Algorithm converged.	0,808	4,928
		Pneumonia bacterial	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Pneumonia viral	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Rectal abscess	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sinusitis	--	1329	100	4	0,301	1332	100	3	0,225	1,337	Algorithm converged.	0,299	5,987	0,076	Algorithm converged.	-0,314	0,465	1,336	Algorithm converged.	0,3	5,959	0,7259		0,748	Algorithm converged.	0,168	3,337
		Superinfection bacterial	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Tooth abscess	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper respiratory tract infection	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Urinary tract infection	--	1329	100	4	0,301	1332	100	1	0,075	4,018	Algorithm converged.	0,449	35,997	0,226	Algorithm converged.	-0,103	0,555	4,009	Algorithm converged.	0,449	35,821	0,2179		0,249	Algorithm converged.	0,028	2,229

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Injury, poisoning and procedural complications	--	--	1329	100	7	0,527	1332	100	1	0,075	7,048	Algorithm converged.	0,866	57,361	0,452	Algorithm converged.	0,036	0,868	7,016	Algorithm converged.	0,864	56,944	0,0386		0,143	Algorithm converged.	0,018	1,157
	Ankle fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Cervical vertebral fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Contusion	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Fall	--	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
	Gastrointestinal anastomotic stenosis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infusion related reaction	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Ligament sprain	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Skin laceration	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Spinal compression fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Tibia fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Upper limb fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Investigations	--	--	1329	100	26	1,956	1332	100	23	1,727	1,136	Algorithm converged.	0,645	2,001	0,23	Algorithm converged.	-0,792	1,251	1,133	Algorithm converged.	0,65	1,975	0,6596		0,883	Algorithm converged.	0,506	1,539
	Activated partial thromboplastin time prolonged	--	--	1329	100	7	0,527	1332	100	7	0,526	1,002	Algorithm converged.	0,351	2,865	0,001	Algorithm converged.	-0,549	0,551	1,002	Algorithm converged.	0,353	2,849	0,9966		0,998	Algorithm converged.	0,351	2,837
	Alanine aminotransferase increased	--	--	1329	100	4	0,301	1332	100	4	0,3	1,002	Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002	Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
	Aspartate aminotransferase increased	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk			
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Bleeding time prolonged	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	--	1329	100	5	0,376	1332	100	2	0,15	2,511		Algorithm converged.	0,486	12,967	0,226	Algorithm converged.	-0,163	0,615	2,506		Algorithm converged.	0,487	12,892	0,288		0,399	Algorithm converged.	0,078	2,053
		Blood lactate dehydrogenase increased	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	--	1329	100	7	0,527	1332	100	7	0,526	1,002		Algorithm converged.	0,351	2,865	0,001	Algorithm converged.	-0,549	0,551	1,002		Algorithm converged.	0,353	2,849	0,9966		0,998	Algorithm converged.	0,351	2,837
		Fibrin D dimer increased	--	1329	100	7	0,527	1332	100	9	0,676	0,778		Algorithm converged.	0,289	2,096	-0,149	Algorithm converged.	-0,736	0,438	0,78		Algorithm converged.	0,291	2,087	0,6193		1,283	Algorithm converged.	0,479	3,434
		Heart rate decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	--	1329	100	2	0,15	1332	100	2	0,15	1,002		Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002		Algorithm converged.	0,141	7,105	1		0,998	Algorithm converged.	0,141	7,073
		International normalised ratio increased	--	1329	100	2	0,15	1332	100	1	0,075	2,006		Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005		Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
		Prothrombin time prolonged	--	1329	100	2	0,15	1332	100	1	0,075	2,006		Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005		Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
		Serum ferritin increased	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Transaminases increased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders		--	1329	100	9	0,677	1332	100	13	0,976	0,692		Algorithm converged.	0,295	1,624	-0,299	Algorithm converged.	-0,987	0,389	0,694		Algorithm converged.	0,298	1,618	0,3948		1,441	Algorithm converged.	0,618	3,36
		Dehydration	--	1329	100	0	0	1332	100	6	0,45	NE	*	Algorithm not converged.	NE	NE	-0,45	Algorithm converged.	-0,81	-0,091	NE	*	Algorithm not converged.	NE	NE	0,0311		NE	Algorithm not converged.	NE	NE
		Haemochromatosis	--	1329	100	1	0,075	1332	100	3	0,225	0,334		Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334		Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		Hyperglycaemia	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyperkalaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	0,075	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Hyponatraemia	--	1329	100	2	0,15	1332	100	3	0,225	0,668		Algorithm converged.	0,111	4,002	-0,075	-0,404	0,254	0,668		Algorithm converged.	0,112	3,992	1		1,497	Algorithm converged.	0,25	8,942
		Malnutrition	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Musculoskeletal and connective tissue disorders	--	--	1329	100	4	0,301	1332	100	10	0,751	0,399		Algorithm converged.	0,125	1,276	-0,45	-0,999	0,099	0,401		Algorithm converged.	0,126	1,275	0,1784		2,494	Algorithm converged.	0,784	7,933
		Arthralgia	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Arthritis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Back pain	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Costochondritis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Joint effusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Myalgia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pain in extremity	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Squamous cell carcinoma of skin	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	12	0,903	1332	100	11	0,826	1,094		Algorithm converged.	0,481	2,489	0,077	Algorithm converged.	-0,626	0,781	1,093		Algorithm converged.	0,484	2,469	0,8299		0,915	Algorithm converged.	0,405	2,065
		Ageusia	--	1329	100	1	0,075	1332	100	3	0,225	0,334		Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334		Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		Anosmia	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Bell's palsy	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Dementia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Dizziness	--	1329	100	2	0,15	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE	*	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	3	0,226	1332	100	4	0,3	0,751		Algorithm converged.	0,168	3,363	-0,075	Algorithm converged.	-0,464	0,315	0,752		Algorithm converged.	0,169	3,352	1		1,33	Algorithm converged.	0,298	5,932
		Hypogeusia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyposmia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Parosmia	--	1329	100	2	0,15	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE	*	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Presyncope	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tremor	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Ectopic pregnancy	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pregnancy	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	1329	100	4	0,301	1332	100	3	0,225	1,337	Algorithm converged.	0,299	5,987	0,076	Algorithm converged.	-0,314	0,465	1,336	Algorithm converged.	0,3	5,959	0,7259		0,748	Algorithm converged.	0,168	3,337		
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935		
		Insomnia	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98		
		Mental status changes	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739		
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935		
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495		
		Heavy menstrual bleeding	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Testicular pain	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	27	2,032	1332	100	41	3,078	0,653	Algorithm converged.	0,399	1,068	-1,046	Algorithm converged.	-2,245	0,152	0,66	Algorithm converged.	0,408	1,066	0,0872		1,515	Algorithm converged.	0,938	2,448		
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Acute respiratory failure	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Asthma	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Bronchial secretion retention	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Bronchospasm	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cough	--	1329	100	11	0,828	1332	100	8	0,601	1,381		Algorithm converged.	0,554	3,445	0,227	Algorithm converged.	-0,413	0,867	1,378		Algorithm converged.	0,556	3,415	0,4867		0,726	Algorithm converged.	0,293	1,798
		Dyspnoea	--	1329	100	8	0,602	1332	100	16	1,201	0,498		Algorithm converged.	0,212	1,168	-0,599	Algorithm converged.	-1,317	0,119	0,501		Algorithm converged.	0,215	1,167	0,1021		1,995	Algorithm converged.	0,857	4,647
		Dyspnoea exertional	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Epistaxis	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Hypoxia	--	1329	100	2	0,15	1332	100	6	0,45	0,333		Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334		Algorithm converged.	0,068	1,652	0,2883		2,993	Algorithm converged.	0,605	14,803
		Nasal congestion	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Oropharyngeal pain	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Productive cough	--	1329	100	2	0,15	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE	*	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Pulmonary congestion	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Respiratory distress	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Respiratory tract congestion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Sinus congestion	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
	Skin and subcutaneous tissue disorders	--	--	1329	100	6	0,451	1332	100	6	0,45	1,002	Algorithm converged.	0,322	3,116	0,001	Algorithm converged.	-0,508	0,51	1,002		Algorithm converged.	0,324	3,1	0,9969		0,998	Algorithm converged.	0,323	3,086
		Acne	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pruritus	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Rash	--	1329	100	6	0,451	1332	100	4	0,3	1,506	Algorithm converged.	0,424	5,348	0,151	Algorithm converged.	-0,314	0,616	1,503		Algorithm converged.	0,425	5,315	0,5477		0,665	Algorithm converged.	0,188	2,352
	Surgical and medical procedures	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	--	1329	100	2	0,15	1332	100	5	0,375	0,4	Algorithm converged.	0,077	2,065	-0,225	Algorithm converged.	-0,614	0,164	0,401		Algorithm converged.	0,078	2,063	0,4525		2,494	Algorithm converged.	0,485	12,834
		Flushing	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypertension	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334		Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	Blood and lymphatic system disorders	--	--	1329	100	6	0,451	1332	100	2	0,15	3,016	Algorithm converged.	0,608	14,969	0,301	Algorithm converged.	-0,115	0,717	3,007	Algorithm converged.	0,608	14,87	0,1786		0,333	Algorithm converged.	0,067	1,645
	Eosinophilia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Iron deficiency anaemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Leukocytosis	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Leukopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Lymphopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Thrombocytopenia	--	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
	Thrombocytosis	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
	Cardiac disorders	--	--	1329	100	4	0,301	1332	100	6	0,45	0,667	Algorithm converged.	0,188	2,37	-0,149	Algorithm converged.	-0,614	0,315	0,668	Algorithm converged.	0,189	2,362	0,7534		1,497	Algorithm converged.	0,423	5,291
	Acute myocardial infarction	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Angina pectoris	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Cardiac failure congestive	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Coronary artery disease	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Palpitations	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Sinus tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Eye disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cataract	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	9	0,677	1332	100	15	1,126	0,599	Algorithm converged.	0,261	1,373	-0,449	Algorithm converged.	-1,167	0,269	0,601	Algorithm converged.	0,264	1,369	0,2208		1,663	Algorithm converged.	0,73	3,787
	Abdominal distension	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Abdominal pain	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Abdominal pain upper	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Chronic gastritis	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Constipation	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Diarrhoea	--	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
	Gastric ulcer	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Gastritis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastroesophageal reflux disease	--	--	1329	100	2	0,15	1332	100	2	0,15	1,002	Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002	Algorithm converged.	0,141	7,105	1		0,998	Algorithm converged.	0,141	7,073
	Nausea	--	--	1329	100	4	0,301	1332	100	4	0,3	1,002	Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002	Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
	Peptic ulcer perforation	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vomiting	--	--	1329	100	0	0	1332	100	5	0,375	NE *	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE *	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	9	0,677	1332	100	19	1,426	0,471	Algorithm converged.	0,212	1,045	-0,749	Algorithm converged.	-1,524	0,025	0,475	Algorithm converged.	0,216	1,045	0,0583		2,106	Algorithm converged.	0,956	4,639
	Chest discomfort	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Death	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Fatigue	--	1329	100	2	0,15	1332	100	3	0,225	0,668		Algorithm converged.	0,111	4,002	-0,075	Algorithm converged.	-0,404	0,254	0,668		Algorithm converged.	0,112	3,992	1		1,497	Algorithm converged.	0,25	8,942
		Fever neonatal Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Oedema peripheral	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Pain	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Peripheral swelling	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Pyrexia	--	1329	100	2	0,15	1332	100	6	0,45	0,333		Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334		Algorithm converged.	0,068	1,652	0,2883		2,993	Algorithm converged.	0,605	14,803
		Swelling face	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Immune system disorders	--	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Seasonal allergy	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	22	1,655	1332	100	31	2,327	0,706		Algorithm converged.	0,407	1,227	-0,672	Algorithm converged.	-1,733	0,389	0,711		Algorithm converged.	0,414	1,222	0,2149		1,406	Algorithm converged.	0,818	2,415
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Sex	Blood and lymphatic system disorders	--	Male	641	48,232	2	0,312	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,312	Algorithm converged.	-0,12	0,744	NE	*	Algorithm not converged.	NE	NE	0,4996	0,2478	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	4	0,581	698	52,402	2	0,287	2,035	Algorithm converged.	0,372	11,147	0,295	Algorithm converged.	-0,398	0,988	2,029	Algorithm converged.	0,373	11,042	0,4489		0,493	Algorithm converged.	0,091	2,682			
	Eosinophilia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Iron deficiency anaemia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Leukocytosis		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Leukopenia		Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Lymphopenia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Thrombocytopenia		Male	641	48,232	2	0,312	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,312	Algorithm converged.	-0,12	0,744	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Thrombocytosis		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	1	0,143	2,032	Algorithm converged.	0,184	22,462	0,147	Algorithm converged.	-0,343	0,638	2,029	Algorithm converged.	0,184	22,325	0,622		0,493	Algorithm converged.	0,045	5,423			

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Cardiac disorders	--	Male	641	48,232	4	0,624	634	47,598	2	0,315	1,984	Algorithm converged.	0,362	10,872	0,309	Algorithm converged.	-0,441	1,058	1,978	Algorithm converged.	0,364	10,762	0,6868	0,0164	0,506	Algorithm converged.	0,093	2,75
			Female	688	51,768	0	0	698	52,402	4	0,573	NE *	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,133	-0,013	NE *	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Angina pectoris		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989	Algorithm converged.	0,062	15,779	1	0,3101	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Palpitations		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Sinus tachycardia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Tachycardia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Eye disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Cataract	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	641	48,232	4	0,624	634	47,598	6	0,946	0,657		Algorithm converged.	0,185	2,34	-0,322		Algorithm converged.	-1,292	0,647	0,659		Algorithm converged.	0,187	2,325	0,5452	0,8535	1,517		Algorithm converged.	0,43	5,349
			Female	688	51,768	5	0,727	698	52,402	9	1,289	0,56		Algorithm converged.	0,187	1,681	-0,563		Algorithm converged.	-1,613	0,488	0,564		Algorithm converged.	0,19	1,673	0,4217		1,774		Algorithm converged.	0,598	5,267
		Abdominal distension	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Abdominal pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
		Abdominal pain upper	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Chronic gastritis	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Constipation	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986		Algorithm converged.	0,062	15,727	
		Diarrhoea	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	
		Gastric ulcer	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastritis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,9899	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986		Algorithm converged.	0,062	15,727	
		Nausea	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,9876	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	3	0,436	698	52,402	3	0,43	1,015		Algorithm converged.	0,204	5,044	0,006		Algorithm converged.	-0,685	0,698	1,015		Algorithm converged.	0,205	5,009	1	0,986		Algorithm converged.	0,2	4,867	
		Peptic ulcer perforation	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Vomiting	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	Male	641	48,232	4	0,624	634	47,598	6	0,946	0,657		Algorithm converged.	0,185	2,34	-0,322	Algorithm converged.	-1,292	0,647	0,659		Algorithm converged.	0,187	2,325	0,5452	0,5278	1,517	Algorithm converged.	0,43	5,349	
			Female	688	51,768	5	0,727	698	52,402	13	1,862	0,386		Algorithm converged.	0,137	1,088	-1,136	Algorithm converged.	-2,323	0,051	0,39		Algorithm converged.	0,14	1,089	0,0943		2,563	Algorithm converged.	0,919	7,15	
		Chest discomfort	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Death	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Fatigue	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,1377	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	3	0,43	0,337		Algorithm converged.	0,035	3,25	-0,284	Algorithm converged.	-0,847	0,278	0,338		Algorithm converged.	0,035	3,243	0,6245		2,957	Algorithm converged.	0,308	28,358	
		Fever neonatal	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Multiple organ dysfunction syndrome	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Non-cardiac chest pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507		Algorithm converged.	0,046	5,599	-0,141		Algorithm converged.	-0,629	0,347	0,507		Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69
		Oedema peripheral	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494		Algorithm converged.	0,045	5,459	-0,159		Algorithm converged.	-0,692	0,373	0,495		Algorithm converged.	0,045	5,44	0,6227	1	2,022	Algorithm converged.	0,184	22,244
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peripheral swelling	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507		Algorithm converged.	0,046	5,599	-0,141		Algorithm converged.	-0,629	0,347	0,507		Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69
		Pyrexia	Male	641	48,232	2	0,312	634	47,598	4	0,631	0,493		Algorithm converged.	0,09	2,701	-0,319		Algorithm converged.	-1,071	0,434	0,495		Algorithm converged.	0,091	2,69	0,4497	0,2478	2,022	Algorithm converged.	0,372	11,001
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Swelling face	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hepatobiliary disorders	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hyperbilirubinaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Immune system disorders	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Seasonal allergy	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Infections and infestations	Male	641	48,232	15	2,34	634	47,598	29	4,574	0,5		Algorithm converged.	0,265	0,942	-2,234	Algorithm converged.	-4,238	-0,23	0,512		Algorithm converged.	0,277	0,945	0,0289	0,9629	1,955	Algorithm converged.	1,058	3,61	
			Female	688	51,768	18	2,616	698	52,402	35	5,014	0,509		Algorithm converged.	0,285	0,908	-2,398	Algorithm converged.	-4,409	-0,387	0,522		Algorithm converged.	0,298	0,912	0,02		1,917	Algorithm converged.	1,096	3,351	
		Bacteraemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Breast abscess	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Bronchitis	Male	641	48,232	3	0,468	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,468	Algorithm converged.	-0,06	0,996	NE	*	Algorithm not converged.	NE	NE	0,2494	0,1377	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		COVID-19	Male	641	48,232	3	0,468	634	47,598	12	1,893	0,244		Algorithm converged.	0,068	0,868	-1,425	Algorithm converged.	-2,61	-0,24	0,247		Algorithm converged.	0,07	0,872	0,0199	0,9159	4,044	Algorithm converged.	1,147	14,263	
			Female	688	51,768	4	0,581	698	52,402	15	2,149	0,266		Algorithm converged.	0,088	0,806	-1,568	Algorithm converged.	-2,784	-0,351	0,271		Algorithm converged.	0,09	0,811	0,0185		3,696	Algorithm converged.	1,233	11,081	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		COVID-19 pneumonia	Male	641	48,232	2	0,312	634	47,598	4	0,631	0,493	Algorithm converged.	0,09	2,701	-0,319	Algorithm converged.	-1,071	0,434	0,495	Algorithm converged.	0,091	2,69	0,4497	0,9818	2,022	Algorithm converged.	0,372	11,001	
			Female	688	51,768	3	0,436	698	52,402	6	0,86	0,505	Algorithm converged.	0,126	2,028	-0,424	Algorithm converged.	-1,267	0,42	0,507	Algorithm converged.	0,127	2,02	0,5065		1,971	Algorithm converged.	0,495	7,851	
		Cellulitis	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Clostridium difficile colitis	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Gastroenteritis	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Kidney infection	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Lung abscess	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Osteomyelitis acute	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Pharyngitis streptococcal	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0516	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE *	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pneumonia	Male	641	48,232	6	0,936	634	47,598	8	1,262	0,739	Algorithm converged.	0,255	2,143	-0,326	Algorithm converged.	-1,471	0,819	0,742	Algorithm converged.	0,259	2,126	0,5769	0,1781	1,348	Algorithm converged.	0,47	3,863
			Female	688	51,768	1	0,145	698	52,402	6	0,86	0,168	Algorithm converged.	0,02	1,398	-0,714	Algorithm converged.	-1,456	0,027	0,169	Algorithm converged.	0,02	1,401	0,1241		5,914	Algorithm converged.	0,714	48,995
		Pneumonia bacterial	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973	0,3023	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015	Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015	Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727
		Pneumonia viral	Male	641	48,232	0	0	634	47,598	2	0,315	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE *	Algorithm not converged.	NE	NE	0,2471	0,0496	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE *	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Rectal abscess	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sinusitis	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494	Algorithm converged.	0,045	5,459	-0,159	Algorithm converged.	-0,692	0,373	0,495	Algorithm converged.	0,045	5,44	0,6227	0,2574	2,022	Algorithm converged.	0,184	22,244
			Female	688	51,768	3	0,436	698	52,402	1	0,143	3,053	Algorithm converged.	0,317	29,418	0,293	Algorithm converged.	-0,274	0,859	3,044	Algorithm converged.	0,317	29,188	0,3709		0,329	Algorithm converged.	0,034	3,151
		Superinfection bacterial	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tooth abscess	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE *	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Upper respiratory tract infection	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	4	0,581	698	52,402	1	0,143	4,076		Algorithm converged.	0,454	36,56	0,438		Algorithm converged.	-0,195	1,072	4,058		Algorithm converged.	0,455	36,216	0,2147		0,246		Algorithm converged.	0,028	2,199
		Injury, poisoning and procedural complications	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981		Algorithm converged.	0,179	21,904	0,154		Algorithm converged.	-0,377	0,685	1,978		Algorithm converged.	0,18	21,761	1	0,1342	0,506		Algorithm converged.	0,046	5,561
			Female	688	51,768	5	0,727	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,727		Algorithm converged.	0,092	1,361	NE	*	Algorithm not converged.	NE	NE	0,0299		NE		Algorithm not converged.	NE	NE
		Ankle fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Cervical vertebral fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Contusion	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Fall	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,291		Algorithm converged.	-0,112	0,693	NE	*	Algorithm not converged.	NE	NE	0,2462		NE		Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infusion related reaction	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Skin laceration	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Tibia fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
	Investigations	--	Male	641	48,232	14	2,184	634	47,598	13	2,05	1,067		Algorithm converged.	0,497	2,288	0,134		Algorithm converged.	-1,447	1,714	1,065		Algorithm converged.	0,505	2,248	0,8685	0,8148	0,939		Algorithm converged.	0,445	1,981
			Female	688	51,768	12	1,744	698	52,402	10	1,433	1,221		Algorithm converged.	0,524	2,846	0,312		Algorithm converged.	-1,005	1,628	1,217		Algorithm converged.	0,529	2,799	0,6428		0,821		Algorithm converged.	0,357	1,889

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Activated partial thromboplastin time prolonged	Male	641	48,232	2	0,312	634	47,598	3	0,473	0,658	Algorithm converged.	0,11	3,953	-0,161	Algorithm converged.	-0,848	0,526	0,659	Algorithm converged.	0,111	3,933	0,6853	0,5597	1,517	Algorithm converged.	0,254	9,046
			Female	688	51,768	5	0,727	698	52,402	4	0,573	1,27	Algorithm converged.	0,34	4,75	0,154	Algorithm converged.	-0,693	1	1,268	Algorithm converged.	0,342	4,703	0,7515		0,789	Algorithm converged.	0,213	2,924
		Alanine aminotransferase increased	Male	641	48,232	3	0,468	634	47,598	2	0,315	1,486	Algorithm converged.	0,247	8,923	0,153	Algorithm converged.	-0,533	0,838	1,484	Algorithm converged.	0,249	8,849	1	0,4719	0,674	Algorithm converged.	0,113	4,02
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507	Algorithm converged.	0,046	5,599	-0,141	Algorithm converged.	-0,629	0,347	0,507	Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69
		Aspartate aminotransferase increased	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,3101	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015	Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015	Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727
		Bleeding time prolonged	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE *	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	Male	641	48,232	5	0,78	634	47,598	2	0,315	2,484	Algorithm converged.	0,48	12,852	0,465	Algorithm converged.	-0,344	1,273	2,473	Algorithm converged.	0,482	12,698	0,4519	1	0,404	Algorithm converged.	0,079	2,077
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood lactate dehydrogenase increased	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		C-reactive protein increased	Male	641	48,232	3	0,468	634	47,598	5	0,789	0,592	Algorithm converged.	0,141	2,486	-0,321	Algorithm converged.	-1,189	0,547	0,593	Algorithm converged.	0,142	2,473	0,5042	0,265	1,685	Algorithm converged.	0,404	7,021
			Female	688	51,768	4	0,581	698	52,402	2	0,287	2,035	Algorithm converged.	0,372	11,147	0,295	Algorithm converged.	-0,398	0,988	2,029	Algorithm converged.	0,373	11,042	0,4489		0,493	Algorithm converged.	0,091	2,682
		Fibrin D dimer increased	Male	641	48,232	3	0,468	634	47,598	4	0,631	0,741	Algorithm converged.	0,165	3,322	-0,163	Algorithm converged.	-0,975	0,649	0,742	Algorithm converged.	0,167	3,301	0,7244	0,9293	1,348	Algorithm converged.	0,303	5,999
			Female	688	51,768	4	0,581	698	52,402	5	0,716	0,811	Algorithm converged.	0,217	3,031	-0,135	Algorithm converged.	-0,98	0,71	0,812	Algorithm converged.	0,219	3,01	1		1,232	Algorithm converged.	0,332	4,569
		Heart rate decreased	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494	Algorithm converged.	0,045	5,459	-0,159	Algorithm converged.	-0,692	0,373	0,495	Algorithm converged.	0,045	5,44	0,6227	0,1855	2,022	Algorithm converged.	0,184	22,244
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE *	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	1	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Prothrombin time prolonged	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	1	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Serum ferritin increased	Male	641	48,232	0	0	634	47,598	3	0,473	NE *	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE *	Algorithm not converged.	NE	NE	0,1227		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Transaminases increased	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	Male	641	48,232	5	0,78	634	47,598	5	0,789	0,989		Algorithm converged.	0,285	3,433	-0,009		Algorithm converged.	-0,977	0,96	0,989		Algorithm converged.	0,288	3,4	1	0,4435	1,011		Algorithm converged.	0,294	3,475
			Female	688	51,768	4	0,581	698	52,402	8	1,146	0,504		Algorithm converged.	0,151	1,683	-0,565		Algorithm converged.	-1,538	0,408	0,507		Algorithm converged.	0,153	1,677	0,3857		1,971		Algorithm converged.	0,596	6,516
		Dehydration	Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473		Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43		Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE
		Haemochromatosis	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,192	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,291		Algorithm converged.	-0,112	0,693	NE	*	Algorithm not converged.	NE	NE	0,2462		NE		Algorithm not converged.	NE	NE
		Hyperkalaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0973	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,2721	NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			Female	688	51,768	2	0,291	698	52,402	2	0,287	1,015	Algorithm converged.	0,143	7,223	0,004	Algorithm converged.	-0,561	0,569	1,015	Algorithm converged.	0,143	7,182	1		0,986	Algorithm converged.	0,139	6,978
		Malnutrition	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	Male	641	48,232	1	0,156	634	47,598	3	0,473	0,329	Algorithm converged.	0,034	3,168	-0,317	Algorithm converged.	-0,933	0,298	0,33	Algorithm converged.	0,034	3,161	0,3717	0,835	3,033	Algorithm converged.	0,316	29,081
			Female	688	51,768	3	0,436	698	52,402	7	1,003	0,432	Algorithm converged.	0,111	1,679	-0,567	Algorithm converged.	-1,455	0,321	0,435	Algorithm converged.	0,113	1,675	0,3421		2,3	Algorithm converged.	0,597	8,858
		Arthralgia	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507	Algorithm converged.	0,046	5,599	-0,141	Algorithm converged.	-0,629	0,347	0,507	Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69
		Arthritis	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE *	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Back pain	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE *	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE *	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Costochondritis	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE *	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
		Intervertebral disc protrusion	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
		Joint effusion	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE					
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
		Musculoskeletal pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE					
		Myalgia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE					
		Pain in extremity	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE				
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727				
		Rhabdomyolysis	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE					
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	1	1,011	Algorithm converged.	0,063	16,129			
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE				
		Gastric cancer	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE					

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Squamous cell carcinoma of skin	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Nervous system disorders	--	Male	641	48,232	2	0,312	634	47,598	5	0,789	0,394		Algorithm converged.	0,076	2,037	-0,477		Algorithm converged.	-1,289	0,336	0,396		Algorithm converged.	0,077	2,032	0,2852	0,1215	2,528		Algorithm converged.	0,492	12,98
			Female	688	51,768	10	1,453	698	52,402	6	0,86	1,701		Algorithm converged.	0,615	4,706	0,594		Algorithm converged.	-0,533	1,72	1,691		Algorithm converged.	0,618	4,627	0,3009		0,591		Algorithm converged.	0,216	1,618	
		Ageusia	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494		Algorithm converged.	0,045	5,459	-0,159		Algorithm converged.	-0,692	0,373	0,495		Algorithm converged.	0,045	5,44	0,6227	0,414	2,022		Algorithm converged.	0,184	22,244	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Anosmia	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494		Algorithm converged.	0,045	5,459	-0,159		Algorithm converged.	-0,692	0,373	0,495		Algorithm converged.	0,045	5,44	0,6227	1	2,022		Algorithm converged.	0,184	22,244	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Bell's palsy	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Dementia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Dizziness	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	2	0,291	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,291		Algorithm converged.	-0,112	0,693	NE	*	Algorithm not converged.	NE	NE	0,2462		NE		Algorithm not converged.	NE	NE	
		Facial paresis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Headache	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,2605	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	3	0,436	698	52,402	3	0,43	1,015		Algorithm converged.	0,204	5,044	0,006	Algorithm converged.	-0,685	0,698	1,015		Algorithm converged.	0,205	5,009	1		0,986	Algorithm converged.	0,2	4,867
		Hypogeusia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyposmia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Parosmia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,291	Algorithm converged.	-0,112	0,693	NE	*	Algorithm not converged.	NE	NE	0,2462		NE	Algorithm not converged.	NE	NE
		Presyncope	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Syncope	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Tremor	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Pregnancy, puerperium and perinatal conditions	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986	Algorithm converged.	0,062	15,727
Ectopic pregnancy		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE
Pregnancy		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE
Psychiatric disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,1622	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	4	0,581	698	52,402	2	0,287	2,035		Algorithm converged.	0,372	11,147	0,295		Algorithm converged.	-0,398	0,988	2,029		Algorithm converged.	0,373	11,042	0,4489		0,493	Algorithm converged.	0,091
Anxiety		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE
Depression		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986	Algorithm converged.	0,062	15,727
Insomnia		Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,3023	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986	Algorithm converged.	0,062	15,727
Mental status changes		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	0,0331	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0943	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Renal failure	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,3101	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727
		Heavy menstrual bleeding	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Testicular pain	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory, thoracic and mediastinal disorders	--	Male	641	48,232	12	1,872	634	47,598	24	3,785	0,485		Algorithm converged.	0,24	0,978	-1,913	Algorithm converged.	-3,732	-0,095	0,495		Algorithm converged.	0,249	0,98	0,0393	0,2278	2,022	Algorithm converged.	1,02	4,008
			Female	688	51,768	15	2,18	698	52,402	17	2,436	0,893		Algorithm converged.	0,442	1,802	-0,255	Algorithm converged.	-1,836	1,325	0,895		Algorithm converged.	0,451	1,778	0,7518		1,117	Algorithm converged.	0,562	2,219	
		Acute respiratory distress syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Asthma	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		Bronchial secretion retention	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Bronchospasm	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Chronic obstructive pulmonary disease	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Cough	Male	641	48,232	5	0,78	634	47,598	5	0,789	0,989		Algorithm converged.	0,285	3,433	-0,009		Algorithm converged.	-0,977	0,96	0,989		Algorithm converged.	0,288	3,4	1	0,4429	1,011		Algorithm converged.	0,294	3,475
			Female	688	51,768	6	0,872	698	52,402	3	0,43	2,038		Algorithm converged.	0,508	8,182	0,442		Algorithm converged.	-0,405	1,29	2,029		Algorithm converged.	0,51	8,081	0,3389		0,493		Algorithm converged.	0,124	1,963
		Dyspnoea	Male	641	48,232	3	0,468	634	47,598	10	1,577	0,293		Algorithm converged.	0,08	1,071	-1,109		Algorithm converged.	-2,214	-0,005	0,297		Algorithm converged.	0,082	1,073	0,0549	0,2319	3,37		Algorithm converged.	0,932	12,188
			Female	688	51,768	5	0,727	698	52,402	6	0,86	0,844		Algorithm converged.	0,256	2,78	-0,133		Algorithm converged.	-1,067	0,801	0,845		Algorithm converged.	0,259	2,757	1		1,183		Algorithm converged.	0,363	3,858
		Dyspnoea exertional	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Epistaxis	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	1	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	Male	641	48,232	1	0,156	634	47,598	6	0,946	0,164		Algorithm converged.	0,02	1,362	-0,79		Algorithm converged.	-1,604	0,023	0,165		Algorithm converged.	0,02	1,365	0,0682	0,0694	6,066		Algorithm converged.	0,732	50,244
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Nasal congestion	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,3101	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Oropharyngeal pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Pneumothorax spontaneous	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Productive cough	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Pulmonary congestion	Male	641	48,232	2	0,312	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,312	Algorithm converged.	-0,12	0,744	NE	*	Algorithm not converged.	NE	NE	0,4996	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Pulmonary mass	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	1	1,011	Algorithm converged.	0,063	16,129	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Respiratory tract congestion	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinus congestion	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Skin and subcutaneous tissue disorders	--	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	0,5132	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,768	4	0,581	698	52,402	5	0,716	0,811	Algorithm converged.	0,217	3,031	-0,135	Algorithm converged.	-0,98	0,71	0,812	Algorithm converged.	0,219	3,01	1		1,232	Algorithm converged.	0,332	4,569
		Acne	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pruritus	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Rash	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	0,7902	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,768	4	0,581	698	52,402	3	0,43	1,355	Algorithm converged.	0,302	6,076	0,152	Algorithm converged.	-0,596	0,899	1,353	Algorithm converged.	0,304	6,022	0,724		0,739	Algorithm converged.	0,166	3,291
	Surgical and medical procedures	--	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	Male	641	48,232	0	0	634	47,598	2	0,315	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE *	Algorithm not converged.	NE	NE	0,2471	0,1953	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	3	0,43	0,675	Algorithm converged.	0,113	4,055	-0,139	Algorithm converged.	-0,769	0,491	0,676	Algorithm converged.	0,113	4,035	1		1,479	Algorithm converged.	0,248	8,821
		Flushing	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Hypertension	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	3	0,43	0,337		Algorithm converged.	0,035	3,25	-0,284	Algorithm converged.	-0,847	0,278	0,338		Algorithm converged.	0,035	3,243	0,6245		2,957	Algorithm converged.	0,308	28,358	
		May-Thurner syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Age	Blood and lymphatic system disorders	--	18-64	1168	87,886	4	0,342	1183	88,814	1	0,085	4,062	Algorithm converged.	0,453	36,395	0,258	Algorithm converged.	-0,116	0,632	4,051	Algorithm converged.	0,454	36,193	0,2154	0,0972	0,247	Algorithm converged.	0,028	2,205		
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE	
	Eosinophilia		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE	
	Iron deficiency anaemia		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Leukocytosis		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Leukopenia		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Lymphopenia		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombocytopenia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombocytosis	18-64	1168	87,886	2	0,171	1183	88,814	1	0,085	2,027		Algorithm converged.	0,184	22,39	0,087		Algorithm converged.	-0,203	0,376	2,026		Algorithm converged.	0,184	22,309	0,6225		0,494	Algorithm converged.	0,045	5,437
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	18-64	1168	87,886	3	0,257	1183	88,814	3	0,254	1,013		Algorithm converged.	0,204	5,029	0,003		Algorithm converged.	-0,405	0,411	1,013		Algorithm converged.	0,205	5,008	1	0,4606	0,987	Algorithm converged.	0,2	4,882
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	2	5,714	0,33		Algorithm converged.	0,029	3,788	-3,754		Algorithm converged.	-12,333	4,826	0,343		Algorithm converged.	0,032	3,64	0,564		2,914	Algorithm converged.	0,275	30,914
		Acute myocardial infarction	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Angina pectoris	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arrhythmia neonatal	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68		Algorithm converged.	0,041	11,248	-0,896		Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1		1,457	Algorithm converged.	0,094	22,527
		Cardiac failure congestive	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Palpitations	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinus tachycardia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Tachycardia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Eye disorders	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Cataract	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Gastrointestinal disorders	18-64	1168	87,886	9	0,771	1183	88,814	10	0,845	0,911		Algorithm converged.	0,369	2,25	-0,075	Algorithm converged.	-0,798	0,649	0,912		Algorithm converged.	0,372	2,235	0,8396	0,0464	1,097	Algorithm converged.	0,447	2,69
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE	*	Algorithm not converged.	NE	NE	-2,632	Algorithm converged.	-5,57	0,307	NE	*	Algorithm not converged.	NE	NE	0,2469		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE	Algorithm not converged.	NE	NE
		Abdominal distension	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Abdominal pain	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal pain upper	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169		Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic gastritis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Constipation	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Diarrhoea	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169		Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Gastric ulcer	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastritis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013		Algorithm converged.	0,142	7,202	0,002		Algorithm converged.	-0,331	0,335	1,013		Algorithm converged.	0,143	7,178	1		0,987	Algorithm converged.	0,139	6,997
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nausea	18-64	1168	87,886	4	0,342	1183	88,814	2	0,169	2,029		Algorithm converged.	0,371	11,1	0,173		Algorithm converged.	-0,235	0,582	2,026		Algorithm converged.	0,372	11,038	0,4497	0,1803	0,494	Algorithm converged.	0,091	2,69
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754		Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Vomiting	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754		Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		General disorders and administration site conditions	18-64	1168	87,886	8	0,685	1183	88,814	13	1,099	0,621		Algorithm converged.	0,256	1,503	-0,414		Algorithm converged.	-1,173	0,345	0,623		Algorithm converged.	0,259	1,498	0,2862	0,1601	1,604	Algorithm converged.	0,667	3,856
			65-74	110	8,277	1	0,909	114	8,559	3	2,632	0,339		Algorithm converged.	0,035	3,314	-1,722		Algorithm converged.	-5,155	1,71	0,345		Algorithm converged.	0,036	3,271	0,6219		2,895	Algorithm converged.	0,306	27,409

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,846	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE
		Chest discomfort	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Fatigue	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013		Algorithm converged.	0,142	7,202	0,002	Algorithm converged.	-0,331	0,335	1,013		Algorithm converged.	0,143	7,178	1		0,987	Algorithm converged.	0,139	6,997
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Non-cardiac chest pain	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5965	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oedema peripheral	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5965	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peripheral swelling	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	18-64	1168	87,886	2	0,171	1183	88,814	6	0,507	0,336	Algorithm converged.	0,068	1,671	-0,336	Algorithm converged.	-0,805	0,133	0,338	Algorithm converged.	0,068	1,669	0,2883		2,962	Algorithm converged.	0,599	14,645
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Swelling face	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Hepatobiliary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Immune system disorders	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Seasonal allergy	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	18-64	1168	87,886	22	1,884	1183	88,814	47	3,973	0,464		Algorithm converged.	0,278	0,775	-2,089		Algorithm converged.	-3,448	-0,73	0,474		Algorithm converged.	0,288	0,782	0,0027	0,8148	2,109		Algorithm converged.	1,28	3,477

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	7	6,364	114	8,559	11	9,649	0,636	Algorithm converged.	0,237	1,706	-3,285	Algorithm converged.	-10,37	3,799	0,66	Algorithm converged.	0,265	1,64	0,3669		1,516	Algorithm converged.	0,61	3,77			
			>=75	51	3,837	4	7,843	35	2,628	6	17,143	0,411	Algorithm converged.	0,107	1,582	-9,3	Algorithm converged.	-23,803	5,203	0,458	Algorithm converged.	0,139	1,504	0,3043		2,186	Algorithm converged.	0,665	7,183			
		Bacteraemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Breast abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchitis	18-64	1168	87,886	3	0,257	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,257	Algorithm converged.	-0,033	0,547	NE	*	Algorithm not converged.	NE	NE	0,1225		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037	Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036	Algorithm converged.	0,066	16,365	1		0,965	Algorithm converged.	0,061	15,236			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		COVID-19	18-64	1168	87,886	5	0,428	1183	88,814	19	1,606	0,263	Algorithm converged.	0,098	0,708	-1,178	Algorithm converged.	-1,986	-0,37	0,267	Algorithm converged.	0,1	0,711	0,0064	0,3237	3,752	Algorithm converged.	1,406	10,015			
			65-74	110	8,277	2	1,818	114	8,559	5	4,386	0,404	Algorithm converged.	0,077	2,126	-2,568	Algorithm converged.	-7,081	1,945	0,415	Algorithm converged.	0,082	2,092	0,4462		2,412	Algorithm converged.	0,478	12,174			
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,846	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	18-64	1168	87,886	1	0,086	1183	88,814	4	0,338	0,253	Algorithm converged.	0,028	2,263	-0,253	Algorithm converged.	-0,623	0,118	0,253	Algorithm converged.	0,028	2,262	0,3745	0,7739	3,949	Algorithm converged.	0,442	35,281			
			65-74	110	8,277	2	1,818	114	8,559	3	2,632	0,685	Algorithm converged.	0,112	4,181	-0,813	Algorithm converged.	-4,669	3,043	0,691	Algorithm converged.	0,118	4,056	1		1,447	Algorithm converged.	0,247	8,497			
			>=75	51	3,837	2	3,922	35	2,628	3	8,571	0,435	Algorithm converged.	0,069	2,752	-4,65	Algorithm converged.	-15,345	6,046	0,458	Algorithm converged.	0,081	2,598	0,3931		2,186	Algorithm converged.	0,385	12,412			

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Cellulitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Kidney infection	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lung abscess	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083		Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975		Algorithm converged.	0,179	21,747
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	18-64	1168	87,886	3	0,257	1183	88,814	12	1,014	0,251		Algorithm converged.	0,071	0,893	-0,758		Algorithm converged.	-1,398	-0,117	0,253		Algorithm converged.	0,072	0,895	0,0346	0,0701	3,949		Algorithm converged.	1,117	13,959
			65-74	110	8,277	2	1,818	114	8,559	2	1,754	1,037		Algorithm converged.	0,144	7,494	0,064		Algorithm converged.	-3,406	3,534	1,036		Algorithm converged.	0,149	7,229	1		0,965		Algorithm converged.	0,138	6,731
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	3,922		Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE		Algorithm not converged.	NE	NE
		Pneumonia bacterial	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5965	0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083		Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975		Algorithm converged.	0,179	21,747
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rectal abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sinusitis	18-64	1168	87,886	3	0,257	1183	88,814	2	0,169	1,521		Algorithm converged.	0,254	9,117	0,088		Algorithm converged.	-0,285	0,461	1,519		Algorithm converged.	0,254	9,076	0,6853	0,9743	0,658		Algorithm converged.	0,11	3,932
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037		Algorithm converged.	0,064	16,782	0,032		Algorithm converged.	-2,433	2,497	1,036		Algorithm converged.	0,066	16,365	1		0,965		Algorithm converged.	0,061	15,236
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Superinfection bacterial	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tooth abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper respiratory tract infection	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	18-64	1168	87,886	3	0,257	1183	88,814	1	0,085	3,044		Algorithm converged.	0,316	29,304	0,172		Algorithm converged.	-0,162	0,507	3,039		Algorithm converged.	0,317	29,169	0,3715		0,329		Algorithm converged.	0,034	3,159
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Injury, poisoning and procedural complications	--	18-64	1168	87,886	2	0,171	1183	88,814	1	0,085	2,027	Algorithm converged.	0,184	22,39	0,087	Algorithm converged.	-0,203	0,376	2,026	Algorithm converged.	0,184	22,309	0,6225	0,3566	0,494	Algorithm converged.	0,045	5,437
			65-74	110	8,277	3	2,727	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	2,727	Algorithm converged.	-0,316	5,771	NE *	Algorithm not converged.	NE	NE	0,1168		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	3,922	Algorithm converged.	-1,406	9,249	NE *	Algorithm not converged.	NE	NE	0,5116		NE	Algorithm not converged.	NE	NE
		Ankle fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Contusion	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,171	Algorithm converged.	-0,066	0,408	NE *	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infusion related reaction	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Skin laceration	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Tibia fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Upper limb fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	18-64	1168	87,886	23	1,969	1183	88,814	21	1,775	1,111		Algorithm converged.	0,612	2,02	0,194	Algorithm converged.	-0,902	1,29	1,109		Algorithm converged.	0,617	1,993	0,7286	0,8219	0,901	Algorithm converged.	0,502	1,62	
			65-74	110	8,277	2	1,818	114	8,559	1	0,877	2,093		Algorithm converged.	0,187	23,413	0,941	Algorithm converged.	-2,086	3,968	2,073		Algorithm converged.	0,191	22,533	0,6167		0,482	Algorithm converged.	0,044	5,245	
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68		Algorithm converged.	0,041	11,248	-0,896	Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1		1,457	Algorithm converged.	0,094	22,527	
		Activated partial thromboplastin time prolonged	18-64	1168	87,886	7	0,599	1183	88,814	7	0,592	1,013		Algorithm converged.	0,354	2,897	0,008	Algorithm converged.	-0,614	0,63	1,013		Algorithm converged.	0,356	2,879	0,9809		0,987	Algorithm converged.	0,347	2,806	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	18-64	1168	87,886	3	0,257	1183	88,814	4	0,338	0,759		Algorithm converged.	0,17	3,399	-0,081	Algorithm converged.	-0,521	0,359	0,76		Algorithm converged.	0,17	3,387	1	0,4589	1,316	Algorithm converged.	0,295	5,869	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5874	0,987	Algorithm converged.	0,062	15,766	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Bleeding time prolonged	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm not converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	18-64	1168	87,886	4	0,342	1183	88,814	2	0,169	2,029		Algorithm converged.	0,371	11,1	0,173	Algorithm converged.	-0,235	0,582	2,026		Algorithm converged.	0,372	11,038	0,4497	0,6864	0,494	Algorithm converged.	0,091	2,69
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm not converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood lactate dehydrogenase increased	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	18-64	1168	87,886	6	0,514	1183	88,814	6	0,507	1,013		Algorithm converged.	0,326	3,15	0,007	Algorithm converged.	-0,57	0,583	1,013		Algorithm converged.	0,328	3,131	0,9823	0,1977	0,987	Algorithm converged.	0,319	3,052
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm not converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm not converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Fibrin D dimer increased	18-64	1168	87,886	6	0,514	1183	88,814	7	0,592	0,867		Algorithm converged.	0,291	2,589	-0,078	Algorithm converged.	-0,677	0,521	0,868		Algorithm converged.	0,293	2,575	0,7987	0,4472	1,152	Algorithm converged.	0,388	3,417

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037	Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036	Algorithm converged.	0,066	16,365	1		0,965	Algorithm converged.	0,061	15,236		
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE		
		Heart rate decreased	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Hepatic enzyme increased	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013	Algorithm converged.	0,142	7,202	0,002	Algorithm converged.	-0,331	0,335	1,013	Algorithm converged.	0,143	7,178	1		0,987	Algorithm converged.	0,139	6,997		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		International normalised ratio increased	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5874	0,987	Algorithm converged.	0,062	15,766		
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Prothrombin time prolonged	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5874	0,987	Algorithm converged.	0,062	15,766		
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Serum ferritin increased	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE *	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Transaminases increased	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Weight decreased	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Metabolism and nutrition disorders	18-64	1168	87,886	8	0,685	1183	88,814	6	0,507	1,353		Algorithm converged.	0,468	3,911	0,178	Algorithm converged.	-0,445	0,8	1,35		Algorithm converged.	0,47	3,88	0,5755	0,0505	0,74	Algorithm converged.	0,258	2,128	
			65-74	110	8,277	1	0,909	114	8,559	5	4,386	0,2		Algorithm converged.	0,023	1,74	-3,477	Algorithm converged.	-7,633	0,68	0,207		Algorithm converged.	0,025	1,746	0,2129		4,825	Algorithm converged.	0,573	40,638	
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE	Algorithm not converged.	NE	NE	
		Dehydration	18-64	1168	87,886	0	0	1183	88,814	4	0,338	NE	*	Algorithm not converged.	NE	NE	-0,338	Algorithm converged.	-0,669	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Haemochromatosis	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,3794	0,987	Algorithm converged.	0,062	15,766	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Hyperglycaemia	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171		Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE	*	Algorithm not converged.	NE	NE	-2,632		Algorithm converged.	-5,57	0,307	NE	*	Algorithm not converged.	NE	NE	0,2469		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Malnutrition	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Musculoskeletal and connective tissue disorders	--	18-64	1168	87,886	4	0,342	1183	88,814	9	0,761	0,448	Algorithm converged.	0,138	1,46	-0,418	Algorithm converged.	-1,016	0,18	0,45	Algorithm converged.	0,139	1,458	0,2656		2,221	Algorithm converged.	0,686	7,194
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthralgia	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthritis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Back pain	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE *	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Costochondritis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Joint effusion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Myalgia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain in extremity	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Gastric cancer			18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Squamous cell carcinoma of skin			18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Nervous system disorders	--		18-64	1168	87,886	9	0,771	1183	88,814	11	0,93	0,827		Algorithm converged.	0,342	2,004	-0,159	Algorithm converged.	-0,901	0,583	0,829		Algorithm converged.	0,345	1,992	0,6742	0,1319	1,207	Algorithm converged.	0,502	2,901	
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
Ageusia			18-64	1168	87,886	1	0,086	1183	88,814	3	0,254	0,337		Algorithm converged.	0,035	3,245	-0,168	Algorithm converged.	-0,5	0,164	0,338		Algorithm converged.	0,035	3,241	0,6247		2,962	Algorithm converged.	0,309	28,434	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Anosmia			18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747	

Test for interaction based on RRR (Log-binomial regression).
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ENDPOINT: Any AEs

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bell's palsy	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dementia	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Dizziness	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Facial paresis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	18-64	1168	87,886	3	0,257	1183	88,814	4	0,338	0,759		Algorithm converged.	0,17	3,399	-0,081		Algorithm converged.	-0,521	0,359	0,76		Algorithm converged.	0,17	3,387	1		1,316		Algorithm converged.	0,295	5,869
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

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				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Hypogeusia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Hyposmia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Parosmia	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE	
		65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Presyncope	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
		65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Syncope	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
		65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Tremor	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ectopic pregnancy	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pregnancy	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	1168	87,886	4	0,342	1183	88,814	3	0,254	1,352		Algorithm converged.	0,302	6,052	0,089		Algorithm converged.	-0,352	0,53	1,35		Algorithm converged.	0,303	6,021	0,7245		0,74	Algorithm converged.	0,166	3,301
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Depression	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Insomnia	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Mental status changes	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
	Renal and urinary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,3794	0,987	Algorithm converged.	0,062	15,766		
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE		
		Acute kidney injury	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Nephrolithiasis	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766		
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Renal failure	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE	
	Reproductive system and breast disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5874	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Heavy menstrual bleeding	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Suppressed lactation	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Testicular pain	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Respiratory, thoracic and mediastinal disorders	--	18-64	1168	87,886	22	1,884	1183	88,814	30	2,536	0,738	Algorithm converged.	0,423	1,287	-0,652	Algorithm converged.	-1,84	0,535	0,743	Algorithm converged.	0,431	1,28	0,2823	0,0536	1,346	Algorithm converged.	0,781	2,32
			65-74	110	8,277	4	3,636	114	8,559	4	3,509	1,038	Algorithm converged.	0,253	4,256	0,128	Algorithm converged.	-4,735	4,99	1,036	Algorithm converged.	0,266	4,042	1		0,965	Algorithm converged.	0,247	3,763
			>=75	51	3,837	1	1,961	35	2,628	7	20	0,08	Algorithm converged.	0,009	0,684	-18,039	Algorithm converged.	-31,826	-4,252	0,098	Algorithm converged.	0,013	0,762	0,0069		10,2	Algorithm converged.	1,312	79,284
		Acute respiratory distress syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE *	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Asthma	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchial secretion retention	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Bronchospasm	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	NE	NE	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	NE	NE	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Cough	18-64	1168	87,886	11	0,942	1183	88,814	6	0,507	1,865		Algorithm converged.	0,687	5,06	0,435	Algorithm converged.	-0,251	1,121	1,857		Algorithm converged.	0,689	5,004	0,2138	0,1178	0,539	Algorithm converged.	0,2	1,451	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Dyspnoea	18-64	1168	87,886	7	0,599	1183	88,814	11	0,93	0,642		Algorithm converged.	0,248	1,663	-0,331	Algorithm converged.	-1,034	0,373	0,645		Algorithm converged.	0,251	1,657	0,358	0,0807	1,552	Algorithm converged.	0,604	3,988	
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037		Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036		Algorithm converged.	0,066	16,365	1		0,965	Algorithm converged.	0,061	15,236	
			>=75	51	3,837	0	0	35	2,628	4	11,429	NE	*	Algorithm not converged.	NE	NE	-11,429	Algorithm converged.	-21,969	-0,888	NE	*	Algorithm not converged.	NE	NE	0,0247		NE	Algorithm not converged.	NE	NE	
		Dyspnoea exertional	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Epistaxis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	1168	87,886	2	0,171	1183	88,814	5	0,423	0,404		Algorithm converged.	0,078	2,087	-0,251	Algorithm converged.	-0,691	0,188	0,405		Algorithm converged.	0,079	2,084	0,4525	0,7366	2,468	Algorithm converged.	0,48	12,697	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nasal congestion	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oropharyngeal pain	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Productive cough	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pulmonary congestion	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68		Algorithm converged.	0,041	11,248	-0,896	Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1	1,457	Algorithm converged.	0,094	22,527	
		Respiratory distress	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory tract congestion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinus congestion	18-64	1168	87,886	0	0	1183	88,814	4	0,338	NE	*	Algorithm not converged.	NE	NE	-0,338	Algorithm converged.	-0,669	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Skin and subcutaneous tissue disorders	18-64	1168	87,886	4	0,342	1183	88,814	5	0,423	0,81		Algorithm converged.	0,217	3,023	-0,08	Algorithm converged.	-0,579	0,419	0,81		Algorithm converged.	0,218	3,01	1	0,0918	1,234	Algorithm converged.	0,332	4,584
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Acne	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pruritus	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rash	18-64	1168	87,886	4	0,342	1183	88,814	3	0,254	1,352		Algorithm converged.	0,302	6,052	0,089	Algorithm converged.	-0,352	0,53	1,35		Algorithm converged.	0,303	6,021	0,7245	0,1069	0,74	Algorithm converged.	0,166	3,301
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Surgical and medical procedures	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Vascular disorders	--	18-64	1168	87,886	2	0,171	1183	88,814	4	0,338	0,506	Algorithm converged.	0,092	2,766	-0,167	Algorithm converged.	-0,574	0,24	0,506	0,093	2,76	0,6871		1,975	Algorithm converged.	0,362	10,76	
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	NE	0,407		NE	Algorithm not converged.	NE	NE		
		Flushing	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hypertension	18-64	1168	87,886	1	0,086	1183	88,814	3	0,254	0,337	Algorithm converged.	0,035	3,245	-0,168	Algorithm converged.	-0,5	0,164	0,338	0,035	3,241	0,6247		2,962	Algorithm converged.	0,309	28,434	
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Baseline viral load categories	Blood and lymphatic system disorders	--	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951	Algorithm converged.	0,176	21,612	0,263	Algorithm converged.	-0,661	1,187	1,946	Algorithm converged.	0,177	21,366	1	0,1689	0,514	Algorithm converged.	0,047	5,642		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,508	Algorithm converged.	-0,065	1,082	NE	*	Algorithm not converged.	NE	NE	0,2498		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Eosinophilia		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Iron deficiency anaemia		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Leukocytosis		<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Leukopenia	<=10 ⁴ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁴ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lymphopenia	<=10 ⁴ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁴ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombocytopenia	<=10 ⁴ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁴ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,339	*	Algorithm not converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Thrombocytosis	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973	Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973	Algorithm converged.	0,061	15,496	1		1,028	Algorithm converged.	0,065	16,369		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37	Algorithm converged.	0,038	3,588	-0,917	Algorithm converged.	-2,877	1,043	0,373	Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52		
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	2	0,357	1,428	Algorithm converged.	0,238	8,581	0,152	Algorithm converged.	-0,605	0,909	1,426	Algorithm converged.	0,239	8,504	1		0,701	Algorithm converged.	0,118	4,18		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Angina pectoris	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arrhythmia neonatal	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	*	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Palpitations	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinus tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Eye disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cataract	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	2	0,556	0,973	Algorithm converged.	0,136	6,944	-0,015		Algorithm converged.	-1,086	1,056	0,973		Algorithm converged.	0,138	6,87	1	0,4899	1,028	Algorithm converged.	0,146	7,257
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	4	2,186	0,287	Algorithm converged.	0,032	2,594	-1,549		Algorithm converged.	-4,006	0,908	0,291		Algorithm converged.	0,033	2,58	0,3787	3,432	Algorithm converged.	0,388	30,385	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	5	0,847	561	42,117	7	1,248	0,676		Algorithm converged.	0,213	2,144	-0,4	Algorithm converged.	-1,58	0,779	0,679	Algorithm converged.	0,217	2,127	0,5707		1,472	Algorithm converged.	0,47	4,612		
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,193	10,089	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Abdominal distension	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Abdominal pain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Abdominal pain upper	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Chronic gastritis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	*	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Constipation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	*	Algorithm converged.	0,059	15,237	-0,009	*	Algorithm converged.	-0,49	0,473	0,951	*	Algorithm converged.	0,06	15,165	1	1,052	0,066	16,773	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Diarrhoea	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	*	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	*	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	*	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Gastric ulcer	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastritis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nausea	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008		Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1	0,4442	1,028	Algorithm converged.	0,065	16,369
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905	Algorithm converged.	0,172	21,065	0,161	Algorithm converged.	-0,424	0,745	1,902	Algorithm converged.	0,173	20,914	1		0,526	Algorithm converged.	0,048	5,783
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE	* Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,193	10,089	NE	* Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	* Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	* Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	* Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	* Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	* Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	* Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	* Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	* Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	* Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	* Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10^5 copies/mL	370	27,84	3	0,811	360	27,027	3	0,833	0,973	Algorithm converged.	0,195	4,852	-0,023	Algorithm converged.	-1,333	1,288	0,973	Algorithm converged.	0,198	4,789	1	0,0739	1,028	Algorithm converged.	0,209	5,059
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	3	1,639	NE	* Algorithm not converged.	NE	NE	-1,639	Algorithm converged.	-3,479	0,2	NE	* Algorithm not converged.	NE	NE	0,2522		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	5	2,439	NE	* Algorithm not converged.	NE	NE	-2,439	Algorithm converged.	-4,551	-0,327	NE	* Algorithm not converged.	NE	NE	0,0629		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	6	1,017	561	42,117	8	1,426	0,71	Algorithm converged.	0,245	2,06	-0,409	Algorithm converged.	-1,681	0,863	0,713	Algorithm converged.	0,249	2,042	0,527		1,402	Algorithm converged.	0,49	4,016
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE	* Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Chest discomfort	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fatigue	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951	Algorithm converged.	0,176	21,612	0,263		Algorithm converged.	-0,661	1,187	1,946		Algorithm converged.	0,177	21,366	1		0,514	Algorithm converged.	0,047	5,642
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	NE	NE	1	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	NE	NE	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973	Algorithm converged.	0,061	15,496	1		1,028	Algorithm converged.	0,065	16,369		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	Algorithm converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oedema peripheral	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	Algorithm converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Pain	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peripheral swelling	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1	1,052		NE	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,5689	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	3	0,535	0,633	Algorithm converged.	0,105	3,8	-0,196	Algorithm converged.	-0,96	0,569	0,634	Algorithm converged.	0,106	3,779	0,6794	1,578		NE	Algorithm converged.	0,265	9,406	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Swelling face	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052		Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	NE	NE	0,169	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Immune system disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	NE	NE	-0,278	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	NE	NE	-0,178	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Seasonal allergy	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	NE	NE	-0,278	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	NE	NE	-0,178	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	<=10^5 copies/mL	370	27,84	5	1,351	360	27,027	13	3,611	0,366	Algorithm converged.	0,129	1,036	-2,26	Algorithm converged.	-4,518	-0,002	0,374	Algorithm converged.	0,135	1,039	0,0574	0,1056	2,672	Algorithm converged.	0,962	7,419	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	8	5,096	183	13,739	6	3,279	1,584	Algorithm converged.	0,538	4,667	1,817	Algorithm converged.	-2,483	6,117	1,554	Algorithm converged.	0,551	4,383	0,4013		0,643	Algorithm converged.	0,228	1,815	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	3	1,639	205	15,39	13	6,341	0,246	Algorithm converged.	0,069	0,878	-4,702	Algorithm converged.	-8,512	-0,892	0,259	Algorithm converged.	0,075	0,893	0,0218		3,868	Algorithm converged.	1,12	13,36	
			>10^7 copies/mL	590	44,394	17	2,881	561	42,117	32	5,704	0,49	Algorithm converged.	0,269	0,894	-2,823	Algorithm converged.	-5,169	-0,476	0,505	Algorithm converged.	0,284	0,899	0,0178		1,98	Algorithm converged.	1,112	3,524	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Bacteraemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		Breast abscess	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		Bronchitis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	*	Algorithm not converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	2	1,274	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	1,274	*	Algorithm not converged.	-0,48	3,028	NE	*	Algorithm not converged.	NE	NE	0,2125	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339	*	Algorithm not converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		COVID-19	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	6	1,667	0,321		Algorithm converged.	0,064	1,599	-1,126		Algorithm converged.	-2,645	0,393	0,324		Algorithm converged.	0,066	1,596	0,1719	0,5438	3,083	Algorithm converged.	0,626	15,176
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	2	1,093	0,58		Algorithm converged.	0,052	6,459	-0,456		Algorithm converged.	-2,41	1,498	0,583		Algorithm converged.	0,053	6,367	1	1,716	Algorithm converged.	0,157	18,744	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk					Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	4	1,951	NE	*	Algorithm not converged.	NE	NE	-1,951	Algorithm converged.	-3,845	-0,058	NE	*	Algorithm not converged.	NE	NE	0,1255		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	15	2,674	0,248		Algorithm converged.	0,082	0,753	-1,996	Algorithm converged.	-3,486	-0,506	0,254		Algorithm converged.	0,085	0,759	0,0096		3,944	Algorithm converged.	1,317	11,811	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	<=10 ⁴ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1	0,2965	NE	Algorithm not converged.	NE	NE	
			>10 ⁴ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE	*	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37		Algorithm converged.	0,038	3,588	-0,917	Algorithm converged.	-2,877	1,043	0,373		Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52	
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	5	0,891	0,568		Algorithm converged.	0,135	2,389	-0,383	Algorithm converged.	-1,349	0,584	0,571		Algorithm converged.	0,137	2,376	0,4964		1,753	Algorithm converged.	0,421	7,3	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cellulitis	<=10 ⁴ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁴ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	<=10 ⁴ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁴ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Gastroenteritis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	NE	NE	0,171	NE *	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Kidney infection	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	NE	NE	0,266	NE *	Algorithm not converged.	NE	NE	0,4932	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Lung abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	NE	NE	0,171	NE *	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Osteomyelitis acute	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	3	0,833	NE *	Algorithm not converged.	NE	NE	-0,833	Algorithm converged.	-1,772	0,106	NE	*	Algorithm not converged.	NE	NE	0,1194	0,2308	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	2	1,274	183	13,739	1	0,546	2,348	Algorithm converged.	0,211	26,147	0,727	Algorithm converged.	-1,326	2,781	2,331	Algorithm converged.	0,213	25,466	0,5973		0,429	Algorithm converged.	0,039	4,686		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37	Algorithm converged.	0,038	3,588	-0,917	Algorithm converged.	-2,877	1,043	0,373	Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52		
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	7	1,248	0,54	Algorithm converged.	0,157	1,856	-0,57	Algorithm converged.	-1,702	0,563	0,543	Algorithm converged.	0,16	1,846	0,3749		1,84	Algorithm converged.	0,542	6,253		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rectal abscess	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	NE	NE	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	NE	NE	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Sinusitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	0,3849	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	1	0,546	1,167	Algorithm converged.	0,072	18,806	0,09	Algorithm converged.	-1,549	1,73	1,166	Algorithm converged.	0,074	18,483	1			0,858	Algorithm converged.	0,054	13,604	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905	Algorithm converged.	0,172	21,065	0,161	Algorithm converged.	-0,424	0,745	1,902	Algorithm converged.	0,173	20,914	1			0,526	Algorithm converged.	0,048	5,783	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Superinfection bacterial	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Tooth abscess	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Upper respiratory tract infection	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Urinary tract infection	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	1	0,178	2,862	Algorithm converged.	0,297	27,596	0,33	Algorithm converged.	-0,342	1,002	2,853	Algorithm converged.	0,298	27,342	0,6248		0,351	Algorithm converged.	0,037	3,36		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973	Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973	Algorithm converged.	0,061	15,496	1		1,028	Algorithm converged.	0,065	16,369		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	2	1,093	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	1,093	Algorithm converged.	-0,413	2,599	NE	*	Algorithm not converged.	NE	NE	0,2218		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	4	0,678	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,678	Algorithm converged.	0,016	1,34	NE	*	Algorithm not converged.	NE	NE	0,1248		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ankle fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Cervical vertebral fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	NE	NE	0,169	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Contusion	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	NE	NE	0,169	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Fall	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	NE	NE	0,27	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	NE	NE	0,169	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Gastrointestinal anastomotic stenosis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	NE	NE	-0,278	NE *	Algorithm not converged.	NE	NE	0,4932	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Infusion related reaction	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ligament sprain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	*	Algorithm not converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Skin laceration	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tibia fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Investigations	--	<=10^5 copies/mL	370	27,84	12	3,243	360	27,027	4	1,111	2,983	Algorithm converged.	0,953	9,338	2,132	Algorithm converged.	0,027	4,237	2,919	Algorithm converged.	0,95	8,966	0,0741	0,0041	0,343	Algorithm converged.	0,112	1,052
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	5	2,732	0,228	Algorithm converged.	0,026	1,974	-2,095	Algorithm converged.	-4,765	0,574	0,233	Algorithm converged.	0,028	1,974	0,2229		4,29	Algorithm converged.	0,507	36,329
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	2	1,093	205	15,39	9	4,39	0,241	Algorithm converged.	0,051	1,129	-3,297	Algorithm converged.	-6,481	-0,114	0,249	Algorithm converged.	0,054	1,137	0,0663		4,017	Algorithm converged.	0,879	18,351
			>10^7 copies/mL	590	44,394	11	1,864	561	42,117	4	0,713	2,646	Algorithm converged.	0,837	8,357	1,151	Algorithm converged.	-0,143	2,446	2,615	Algorithm converged.	0,838	8,164	0,1178		0,382	Algorithm converged.	0,122	1,194
			Unknown	29	2,182	0	0	23	1,727	1	4,348	NE *	Algorithm not converged.	NE	NE	-4,348	Algorithm converged.	-12,682	3,986	NE	Algorithm not converged.	NE	NE	0,4423		NE	Algorithm not converged.	NE	NE
		Activated partial thromboplastin time prolonged	<=10^5 copies/mL	370	27,84	5	1,351	360	27,027	1	0,278	4,918	Algorithm converged.	0,572	42,302	1,074	Algorithm converged.	-0,222	2,37	4,865	Algorithm converged.	0,571	41,437	0,2171	0,0437	0,206	Algorithm converged.	0,024	1,751
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE *	Algorithm not converged.	NE	NE	-1,463	Algorithm converged.	-3,107	0,18	NE	Algorithm not converged.	NE	NE	0,2505		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905	Algorithm converged.	0,172	21,065	0,161	Algorithm converged.	-0,424	0,745	1,902	Algorithm converged.	0,173	20,914	1		0,526	Algorithm converged.	0,048	5,783
			Unknown	29	2,182	0	0	23	1,727	1	4,348	NE *	Algorithm not converged.	NE	NE	-4,348	Algorithm converged.	-12,682	3,986	NE	Algorithm not converged.	NE	NE	0,4423		NE	Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	Algorithm not converged.	NE	NE	0,4994	0,2403	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	2	1,093	0,58	Algorithm converged.	0,052	6,459	-0,456	Algorithm converged.	-2,41	1,498	0,583	Algorithm converged.	0,053	6,367	1		1,716	Algorithm converged.	0,157	18,744
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bleeding time prolonged	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	1	4,348	NE *	Algorithm not converged.	NE	NE	-4,348	Algorithm converged.	-12,682	3,986	NE	*	Algorithm not converged.	NE	NE	0,4423		NE	Algorithm not converged.	NE	NE	
		Blood creatine phosphokinase increased	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE *	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,678	*	Algorithm converged.	0,016	1,34	NE	*	Algorithm not converged.	NE	NE	0,1248		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood lactate dehydrogenase increased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	*	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951	*	Algorithm converged.	0,176	21,612	0,263	*	Algorithm converged.	-0,661	1,187	1,946	*	Algorithm converged.	0,177	21,366	1	0,1746	0,514	Algorithm converged.	0,047	5,642
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	*	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	4	1,951	0,276	*	Algorithm converged.	0,031	2,493	-1,405	*	Algorithm converged.	-3,579	0,769	0,28	*	Algorithm converged.	0,032	2,483	0,3758		3,571	Algorithm converged.	0,403	31,658
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	1	0,178	3,823	*	Algorithm converged.	0,426	34,305	0,5	*	Algorithm converged.	-0,249	1,248	3,803	*	Algorithm converged.	0,426	33,925	0,3747		0,263	Algorithm converged.	0,029	2,345
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fibrin D dimer increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	4	1,111	0,484	*	Algorithm converged.	0,088	2,657	-0,571	*	Algorithm converged.	-1,886	0,745	0,486	*	Algorithm converged.	0,09	2,64	0,4453	0,0401	2,056	Algorithm converged.	0,379	11,153
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	*	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463	*	Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	5	0,847	561	42,117	1	0,178	4,786	*	Algorithm converged.	0,557	41,096	0,669	*	Algorithm converged.	-0,149	1,487	4,754	*	Algorithm converged.	0,557	40,567	0,2184		0,21	Algorithm converged.	0,025	1,795

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Heart rate decreased	<=10 ⁵ copies/mL	370	27.84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	*	Algorithm not converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	<=10 ⁵ copies/mL	370	27.84	2	0,541	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,541	*	Algorithm not converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	*	Algorithm not converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	*	Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	<=10 ⁵ copies/mL	370	27.84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	*	Algorithm not converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,339	*	Algorithm not converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Prothrombin time prolonged	<=10 ⁵ copies/mL	370	27.84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	*	Algorithm not converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,339	Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Serum ferritin increased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Transaminases increased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Weight decreased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	NE	NE	0,169	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27,84	4	1,081	360	27,027	1	0,278	3,923	Algorithm converged.	0,436	35,273	0,803	Algorithm converged.	-0,382	1,989	3,892		Algorithm converged.	0,437	34,653	0,3735	0,0635	0,257	Algorithm converged.	0,029	2,288	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	3	1,639	0,385	Algorithm converged.	0,04	3,735	-1,002	Algorithm converged.	-3,224	1,219	0,389		Algorithm converged.	0,041	3,698	0,6272		2,574	Algorithm converged.	0,27	24,495	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	4	1,951	NE	*	Algorithm not converged.	NE	NE	-1,951	Algorithm converged.	-3,845	-0,058	NE	*	Algorithm not converged.	NE	NE	0,1255		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	4	0,678	561	42,117	5	0,891	0,759	Algorithm converged.	0,203	2,841	-0,213	Algorithm converged.	-1,235	0,808	0,761		Algorithm converged.	0,205	2,818	0,7474		1,315	Algorithm converged.	0,355	4,871	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Haemochromatosis	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyperglycaemia	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE				
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Malnutrition	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	3	0,833	0,322		Algorithm converged.	0,033	3,115	-0,563		Algorithm converged.	-1,641	0,515	0,324		Algorithm converged.	0,034	3,103	0,3672	0,8318	3,083	Algorithm converged.	0,322	29,504
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37		Algorithm converged.	0,038	3,588	-0,917		Algorithm converged.	-2,877	1,043	0,373		Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	3	0,535	0,633		Algorithm converged.	0,105	3,8	-0,196		Algorithm converged.	-0,96	0,569	0,634		Algorithm converged.	0,106	3,779	0,6794		1,578	Algorithm converged.	0,265	9,406

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Arthralgia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	2	0,556	NE	*	Algorithm not converged.	NE	NE	-0,556	Algorithm converged.	-1,323	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Arthritis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Back pain	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Costochondritis	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Table with columns for Patient, SOC, PT, Level, Casirivimab/Imdevimab, Placebo, Odds Ratio, Absolute Risk Difference, Relative Risk, and Placebo vs. Casirivimab/Imdevimab. Rows include comparisons for Intervertebral disc protrusion and Joint effusion across different viral load levels.

Test for interaction based on RR (Log-binomial regression). * indicates convergence problem. Result is uninterpretable. Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method. 95% CI for the relative risk use Farrington-Manning method. If np <= 5 in any treatment group, p-value is based on Fisher Exact Test. Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Myalgia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	NE	NE	-0,178	NE	NE	NE	*	NE	NE	NE	0,4874			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Pain in extremity	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	NE	NE	-0,488	NE	NE	NE	*	NE	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	NE	NE	0,169	NE	NE	NE	*	NE	NE	NE	1			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	NE	NE	0,169	NE	NE	NE	*	NE	NE	NE	1			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	NE	NE	NE	*	NE	NE	NE	*	NE	NE	NE			NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Gastric cancer	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Squamous cell carcinoma of skin	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Nervous system disorders	--	<=10^5 copies/mL	370	27.84	3	0,811	360	27.027	1	0,278	2,935	Algorithm converged.	0,304	28,344	0,533	Algorithm converged.	-0,53	1,596	2,919	Algorithm converged.	0,305	27,931	0,6241	0,1218	0,343	Algorithm converged.	0,036	3,278		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE	*	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	4	1,951	0,276		Algorithm converged.	0,031	2,493	-1,405	Algorithm converged.	-3,579	0,769	0,28		Algorithm converged.	0,032	2,483	0,3758		3,571	Algorithm converged.	0,403	31,658	
			>10 ⁷ copies/mL	590	44,394	7	1,186	561	42,117	4	0,713	1,672		Algorithm converged.	0,487	5,743	0,473	Algorithm converged.	-0,644	1,591	1,664		Algorithm converged.	0,49	5,653	0,5483		0,601	Algorithm converged.	0,177	2,042	
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,193	10,089	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Ageusia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE	*	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anosmia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bell's palsy	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dementia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dizziness	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	3,448	Algorithm not converged.	-3,193	10,089	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Facial paresis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Headache	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951	Algorithm converged.	0,176	21,612	0,263	Algorithm converged.	-0,661	1,187	1,946	Algorithm converged.	0,177	21,366	1		0,514	Algorithm converged.	0,047	5,642	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE *	Algorithm not converged.	NE	NE	-1,463	Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,193	10,089	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
		Hypogeusia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hyposmia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Parosmia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Presyncope	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Syncope	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tremor	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ectopic pregnancy	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pregnancy	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Psychiatric disorders	--	<= 10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			> 10^5 copies/mL - <= 10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^6 copies/mL - <= 10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			> 10^7 copies/mL	590	44,394	3	0,508	561	42,117	1	0,178	2,862	Algorithm converged.	0,297	27,596	0,33	Algorithm converged.	-0,342	1,002	2,853	*	Algorithm converged.	0,298	27,342	0,6248		0,351	Algorithm converged.	0,037	3,36
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	<= 10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^5 copies/mL - <= 10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^6 copies/mL - <= 10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	<= 10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^5 copies/mL - <= 10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^6 copies/mL - <= 10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	*	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Insomnia	<= 10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			> 10^5 copies/mL - <= 10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Mental status changes	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052		Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute kidney injury	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Nephrolithiasis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Renal failure	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
	Reproductive system and breast disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905		Algorithm converged.	0,172	21,065	0,161	Algorithm converged.	-0,424	0,745	1,902		Algorithm converged.	0,173	20,914	1	0,526	Algorithm converged.	0,048	5,783	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		Heavy menstrual bleeding	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Testicular pain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	370	27,84	8	2,162	360	27,027	7	1,944	1,114	Algorithm converged.	0,4	3,106	0,218		Algorithm converged.	-1,839	2,275	1,112		Algorithm converged.	0,407	3,035	0,8359	0,4333	0,899	Algorithm converged.	0,33	2,454
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	3	1,911	183	13,739	3	1,639	1,169	Algorithm converged.	0,233	5,875	0,271		Algorithm converged.	-2,552	3,095	1,166		Algorithm converged.	0,239	5,693	1		0,858	Algorithm converged.	0,176	4,19

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	2	1,093	205	15,39	7	3,415	0,313	Algorithm converged.	0,064	1,524	-2,322	Algorithm converged.	-5,228	0,585	0,32	Algorithm converged.	0,067	1,521	0,181			3,124	Algorithm converged.	0,657	14,85		
			>10 ⁷ copies/mL	590	44,394	14	2,373	561	42,117	24	4,278	0,544	Algorithm converged.	0,278	1,062	-1,905	Algorithm converged.	-3,982	0,171	0,555	Algorithm converged.	0,29	1,061	0,0707			1,803	Algorithm converged.	0,942	3,45		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE *	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155			NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Asthma	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973	Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973	Algorithm converged.	0,061	15,496	1			1,028	Algorithm converged.	0,065	16,369		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
		Bronchial secretion retention	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchospasm	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Cough	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	3	0,833	0,647	Algorithm converged.	0,107	3,893	-0,293	Algorithm converged.	-1,493	0,907	0,649	Algorithm converged.	0,109	3,859	0,6824	0,7398	1,542	Algorithm converged.	0,259	9,172	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	2	1,093	205	15,39	2	0,976	1,122	Algorithm converged.	0,156	8,044	0,117	Algorithm converged.	-1,902	2,137	1,12	Algorithm converged.	0,159	7,872	1		0,893	Algorithm converged.	0,127	6,273	
			>10^7 copies/mL	590	44,394	7	1,186	561	42,117	3	0,535	2,233	Algorithm converged.	0,575	8,679	0,652	Algorithm converged.	-0,41	1,714	2,219	Algorithm converged.	0,577	8,537	0,3432		0,451	Algorithm converged.	0,117	1,734	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Dyspnoea	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	2	0,556	0,973	Algorithm converged.	0,136	6,944	-0,015	Algorithm converged.	-1,086	1,056	0,973	Algorithm converged.	0,138	6,87	1	0,5047	1,028	Algorithm converged.	0,146	7,257	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	1	0,546	1,167	Algorithm converged.	0,072	18,806	0,09	Algorithm converged.	-1,549	1,73	1,166	Algorithm converged.	0,074	18,483	1		0,858	Algorithm converged.	0,054	13,604	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	5	0,847	561	42,117	11	1,961	0,427	Algorithm converged.	0,148	1,238	-1,113	Algorithm converged.	-2,478	0,252	0,432	Algorithm converged.	0,151	1,236	0,1327		2,314	Algorithm converged.	0,809	6,617	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Dyspnoea exertional	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Epistaxis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
* indicates convergence problem. Result is uninterpretable.
Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
95% CI for the relative risk use Farrington-Manning method.
If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,0317	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE *	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nasal congestion	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oropharyngeal pain	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Pneumothorax spontaneous	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	NE	NE	0,171	NE *	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Productive cough	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,339	Algorithm converged.	NE	NE	0,808	NE *	Algorithm not converged.	NE	NE	0,4999	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Pulmonary congestion	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	NE	NE	0,799	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,339	Algorithm converged.	NE	NE	0,808	NE *	Algorithm not converged.	NE	NE	0,4999	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Pulmonary mass	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE *	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory tract congestion	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinus congestion	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE *	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE *	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE *	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
	Skin and subcutaneous tissue disorders	--	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	*	Algorithm not converged.	NE	NE	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,1563	NE		Algorithm not converged.	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE	*	Algorithm not converged.	NE	NE	-1,093	*	Algorithm not converged.	NE	NE	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE		Algorithm not converged.	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	1	0,488	1,121		Algorithm converged.	0,07	18,049	0,059		Algorithm converged.	-1,373	1,491	1,12		Algorithm converged.	0,071	17,781	1		0,893		Algorithm converged.	0,056	14,17			
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	3	0,535	0,951		Algorithm converged.	0,191	4,73	-0,026		Algorithm converged.	-0,859	0,807	0,951		Algorithm converged.	0,193	4,691	1		1,052		Algorithm converged.	0,213	5,189			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
		Acne	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	*	Algorithm not converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
		Pruritus	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	*	Algorithm not converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Rash	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,2949	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	1	0,488	1,121		Algorithm converged.	0,07	18,049	0,059	Algorithm converged.	-1,373	1,491	1,12		Algorithm converged.	0,071	17,781	1		0,893	Algorithm converged.	0,056	14,17	
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	2	0,357	1,428		Algorithm converged.	0,238	8,581	0,152	Algorithm converged.	-0,605	0,909	1,426		Algorithm converged.	0,239	8,504	1		0,701	Algorithm converged.	0,118	4,18	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	2	0,556	NE	*	Algorithm not converged.	NE	NE	-0,556	Algorithm converged.	-1,323	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	3	0,535	0,316		Algorithm converged.	0,033	3,045	-0,365		Algorithm converged.	-1,054	0,323	0,317		Algorithm not converged.	0,033	3,038	0,3622	3,155	Algorithm converged.	0,329	30,242	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Flushing	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypertension	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	2	0,556	NE	*	Algorithm not converged.	NE	NE	-0,556		Algorithm converged.	-1,323	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637		Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Thrombophlebitis superficial	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Country	Blood and lymphatic system disorders	--	USA	1237	93,078	6	0,485	1239	93,018	2	0,161	3,015	Algorithm converged.	0,607	14,965	0,324	Algorithm converged.	-0,123	0,771	3,005	Algorithm converged.	0,608	14,859	0,1787	1	0,333	Algorithm converged.	0,067	1,646
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Eosinophilia		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Iron deficiency anaemia		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Leukocytosis		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Leukopenia		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Lymphopenia		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Thrombocytopenia		USA	1237	93,078	2	0,162	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,062	0,386	NE *	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE
	Thrombocytosis		USA	1237	93,078	2	0,162	1239	93,018	1	0,081	2,005	Algorithm converged.	0,182	22,139	0,081	Algorithm converged.	-0,193	0,355	2,003	Algorithm converged.	0,182	22,064	0,6245	1	0,499	Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE			Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Cardiac disorders	--	USA	1237	93,078	4	0,323	1239	93,018	6	0,484	0,667	Algorithm converged.	0,188	2,368	-0,161	Algorithm converged.	-0,66	0,339	0,668	Algorithm converged.	0,189	2,36	0,7534	1	1,498	Algorithm converged.	0,424	5,294
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Acute myocardial infarction		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Angina pectoris		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Arrhythmia neonatal		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Atrial fibrillation		USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Cardiac failure congestive		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Coronary artery disease		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Palpitations		USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Sinus tachycardia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Tachycardia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Eye disorders	--	USA	1237	93,078	0	0	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Cataract	USA	1237	93,078	0	0	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Gastrointestinal disorders	--	USA	1237	93,078	8	0,647	1239	93,018	12	0,969	0,666	Algorithm converged.	0,271	1,634	-0,322	Algorithm converged.	-1,027	0,383	0,668	Algorithm converged.	0,274	1,628	0,3712	0,5642	1,498	Algorithm converged.	0,614	3,651	
			MEX	92	6,922	1	1,087	93	6,982	3	3,226	0,33	Algorithm converged.	0,034	3,229	-2,139	Algorithm converged.	-6,308	2,031	0,337	Algorithm converged.	0,036	3,18	0,6209		2,968	Algorithm converged.	0,314	28,01		
		Abdominal distension	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Abdominal pain	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Abdominal pain upper	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				n	%	Patients with Event		n	%	Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk										
						n	%			n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Chronic gastritis	USA	1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	1	1,087	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	1,087		Algorithm converged.	-1,032	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Constipation	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998		Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Diarrhoea	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Gastric ulcer	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastritis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	USA	1237	93,078	2	0,162	1239	93,018	1	0,081	2,005		Algorithm converged.	0,182	22,139	0,081		Algorithm converged.	-0,193	0,355	2,003		Algorithm converged.	0,182	22,064	0,6245	0,1893	0,499		Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075		Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Nausea	USA	1237	93,078	4	0,323	1239	93,018	4	0,323	1,002		Algorithm converged.	0,25	4,014	0,001		Algorithm converged.	-0,447	0,448	1,002		Algorithm converged.	0,251	3,996	1	1	0,998		Algorithm converged.	0,25	3,983
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Vomiting	USA	1237	93,078	0	0	1239	93,018	5	0,404	NE	*	Algorithm not converged.	NE	NE	-0,404	Algorithm converged.	-0,757	-0,051	NE	*	Algorithm not converged.	NE	NE	0,0622		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	1237	93,078	9	0,728	1239	93,018	16	1,291	0,56		Algorithm converged.	0,247	1,273	-0,564	Algorithm converged.	-1,351	0,223	0,563		Algorithm converged.	0,25	1,27	0,1607	0,114	1,775	Algorithm converged.	0,787	4,001	
			MEX	92	6,922	0	0	93	6,982	3	3,226	NE	*	Algorithm not converged.	NE	NE	-3,226	Algorithm converged.	-6,817	0,365	NE	*	Algorithm not converged.	NE	NE	0,2459		NE	Algorithm not converged.	NE	NE	
		Chest discomfort	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fatigue	USA	1237	93,078	2	0,162	1239	93,018	3	0,242	0,667		Algorithm converged.	0,111	4	-0,08	Algorithm converged.	-0,434	0,273	0,668		Algorithm converged.	0,112	3,989	1	1	1,498	Algorithm converged.	0,251	8,947	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	USA	1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE	*	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
			Level	n	%	Patients with Event	n	%	Patients with Event	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Non-cardiac chest pain	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE
		Oedema peripheral	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE
		Pain	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE
		Peripheral swelling	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE
		Pyrexia	USA	1237	93,078	2	0,162	1239	93,018	5	0,404	0,4	Algorithm converged.	0,077	2,064	-0,242	Algorithm converged.	-0,66	0,176	0,401	Algorithm converged.	0,078	2,061	0,4525	0,4316	2,496	Algorithm converged.	0,485	12,841
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE
		Swelling face	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE
	Hepatobiliary disorders	--	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE
		Cholecystitis acute	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab														
			Level	Patients		Patients with Event		Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
				n	%	n	%																			n	%	n	%	n	%	n	%
		Hyperbilirubinaemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm not converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Immune system disorders	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Seasonal allergy	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	USA	1237	93,078	31	2,506	1239	93,018	57	4,6	0,533		Algorithm converged.	0,342	0,832	-2,094		Algorithm converged.	-3,55	-0,639	0,545		Algorithm converged.	0,354	0,838	0,0049	0,4153	1,836		Algorithm converged.	1,194	2,823
			MEX	92	6,922	2	2,174	93	6,982	7	7,527	0,273		Algorithm converged.	0,055	1,351	-5,353		Algorithm converged.	-11,487	0,781	0,289		Algorithm converged.	0,062	1,354	0,169		3,462		Algorithm converged.	0,739	16,228
		Bacteraemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Breast abscess	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bronchitis	USA	1237	93,078	4	0,323	1239	93,018	1	0,081	4,016		Algorithm converged.	0,448	35,984	0,243		Algorithm converged.	-0,111	0,596	4,006		Algorithm converged.	0,448	35,795	0,218	1	0,25		Algorithm converged.	0,028	2,23
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19	USA	1237	93,078	5	0,404	1239	93,018	21	1,695	0,235		Algorithm converged.	0,088	0,626	-1,291		Algorithm converged.	-2,092	-0,49	0,238		Algorithm converged.	0,09	0,63	0,0024	0,7182	4,193		Algorithm converged.	1,586	11,085
			MEX	92	6,922	2	2,174	93	6,982	6	6,452	0,322		Algorithm converged.	0,063	1,64	-4,278		Algorithm converged.	-10,092	1,537	0,337		Algorithm converged.	0,07	1,626	0,2783		2,968		Algorithm converged.	0,615	14,324

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		COVID-19 pneumonia	USA	1237	93,078	5	0,404	1239	93,018	9	0,726	0,555	Algorithm converged.	0,185	1,66	-0,322	Algorithm converged.	-0,913	0,268	0,556	Algorithm converged.	0,187	1,656	0,4226	0,3586	1,797	Algorithm converged.	0,604	5,347
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cellulitis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Kidney infection	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lung abscess	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab		
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason
Pneumonia	USA	1237	93,078	7	0,566	1239	93,018	14	1,13	0,498	Algorithm converged.	0,2	1,238	-0,564	Algorithm converged.	-1,286	0,158	0,501	Algorithm converged.	0,203	1,237	0,126	1	1,997	Algorithm converged.	0,809	4,93
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pneumonia bacterial	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pneumonia viral	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Rectal abscess	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Sepsis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Sinusitis	USA	1237	93,078	4	0,323	1239	93,018	3	0,242	1,337	Algorithm converged.	0,299	5,984	0,081	Algorithm converged.	-0,337	0,5	1,335	Algorithm converged.	0,3	5,955	0,726	1	0,749	Algorithm converged.	0,168	3,339
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Superinfection bacterial	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Tooth abscess	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk									
			Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Upper respiratory tract infection	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm not converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	USA	1237	93,078	4	0,323	1239	93,018	1	0,081	4,016		Algorithm converged.	0,448	35,984	0,243	Algorithm converged.	-0,111	0,596	4,006		Algorithm converged.	0,448	35,795	0,218	1	0,25		Algorithm converged.	0,028	2,23	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Injury, poisoning and procedural complications	USA	1237	93,078	7	0,566	1239	93,018	1	0,081	7,046		Algorithm converged.	0,866	57,35	0,485	Algorithm converged.	0,038	0,932	7,011		Algorithm converged.	0,864	56,902	0,0386	1	0,143		Algorithm converged.	0,018	1,158	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ankle fracture	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cervical vertebral fracture	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Contusion	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fall	USA	1237	93,078	2	0,162	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,062	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	
		Infusion related reaction	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Skin laceration	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tibia fracture	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Investigations	USA	1237	93,078	26	2,102	1239	93,018	23	1,856	1,135		Algorithm converged.	0,644	2	0,246		Algorithm converged.	-0,852	1,343	1,132		Algorithm converged.	0,65	1,973	0,661	1	0,883		Algorithm converged.	0,507	1,539
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Level	Patients		Patients with Event		Odds Ratio	Convergence Reason	95% CI		Absolute Risk	Convergence Reason	95% CI		Relative Risk	Convergence Reason	95% CI		p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% CI					
				n	%	n	%			n	%			n	%			Lower CL	upper CL					Lower CL	upper CL	Lower CL	upper CL	Lower CL	upper CL
		Activated partial thromboplastin time prolonged	USA	1237	93,078	7	0,566	1239	93,018	7	0,565	1,002	Algorithm converged.	0,35	2,864	0,001	Algorithm converged.	-0,59	0,592	1,002	Algorithm converged.	0,352	2,847	0,9976	1	0,998	Algorithm converged.	0,351	2,838
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	USA	1237	93,078	4	0,323	1239	93,018	4	0,323	1,002	Algorithm converged.	0,25	4,014	0,001	Algorithm converged.	-0,447	0,448	1,002	Algorithm converged.	0,251	3,996	1	1	0,998	Algorithm converged.	0,25	3,983
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	USA	1237	93,078	2	0,162	1239	93,018	1	0,081	2,005	Algorithm converged.	0,182	22,139	0,081	Algorithm converged.	-0,193	0,355	2,003	Algorithm converged.	0,182	22,064	0,6245	1	0,499	Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bleeding time prolonged	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	USA	1237	93,078	5	0,404	1239	93,018	2	0,161	2,51	Algorithm converged.	0,486	12,963	0,243	Algorithm converged.	-0,176	0,661	2,504	Algorithm converged.	0,487	12,882	0,2881	1	0,399	Algorithm converged.	0,078	2,054
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood lactate dehydrogenase increased	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
C-reactive protein increased	USA	1237	93,078	7	0,566	1239	93,018	7	0,565	1,002	Algorithm converged.	0,35	2,864	0,001	Algorithm converged.	-0,59	0,592	1,002	Algorithm converged.	0,352	2,847	0,9976	1	0,998	Algorithm converged.	0,351	2,838		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
Fibrin D dimer increased	USA	1237	93,078	7	0,566	1239	93,018	9	0,726	0,778	Algorithm converged.	0,289	2,095	-0,161	Algorithm converged.	-0,792	0,471	0,779	Algorithm converged.	0,291	2,085	0,6183	1	1,284	Algorithm converged.	0,48	3,436		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
Heart rate decreased	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
Hepatic enzyme increased	USA	1237	93,078	2	0,162	1239	93,018	2	0,161	1,002	Algorithm converged.	0,141	7,122	0	Algorithm converged.	-0,316	0,317	1,002	Algorithm converged.	0,141	7,099	1	1	0,998	Algorithm converged.	0,141	7,076		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
International normalised ratio increased	USA	1237	93,078	2	0,162	1239	93,018	1	0,081	2,005	Algorithm converged.	0,182	22,139	0,081	Algorithm converged.	-0,193	0,355	2,003	Algorithm converged.	0,182	22,064	0,6245	1	0,499	Algorithm converged.	0,045	5,498		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
Prothrombin time prolonged	USA	1237	93,078	2	0,162	1239	93,018	1	0,081	2,005	Algorithm converged.	0,182	22,139	0,081	Algorithm converged.	-0,193	0,355	2,003	Algorithm converged.	0,182	22,064	0,6245	1	0,499	Algorithm converged.	0,045	5,498		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
Serum ferritin increased	USA	1237	93,078	0	0	1239	93,018	3	0,242	NE *	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,516	0,032	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE		
	MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
Transaminases increased	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk											
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	1237	93,078	9	0,728	1239	93,018	13	1,049	0,691		Algorithm converged.	0,294	1,623	-0,322		Algorithm converged.	-1,061	0,417	0,693		Algorithm converged.	0,297	1,616	0,3939	1	1,442		Algorithm converged.	0,619	3,361
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	1237	93,078	0	0	1239	93,018	6	0,484	NE	*	Algorithm not converged.	NE	NE	-0,484		Algorithm converged.	-0,871	-0,098	NE	*	Algorithm not converged.	NE	NE	0,0311		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Haemochromatosis	USA	1237	93,078	1	0,081	1239	93,018	3	0,242	0,333		Algorithm converged.	0,035	3,209	-0,161		Algorithm converged.	-0,477	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995		Algorithm converged.	0,312	28,755
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	USA	1237	93,078	3	0,243	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,243		Algorithm converged.	-0,032	0,517	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperkalaemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998		Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	1237	93,078	2	0,162	1239	93,018	3	0,242	0,667		Algorithm converged.	0,111	4	-0,08		Algorithm converged.	-0,434	0,273	0,668		Algorithm converged.	0,112	3,989	1	1	1,498		Algorithm converged.	0,251	8,947

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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
		Malnutrition	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	USA	1237	93,078	4	0,323	1239	93,018	10	0,807	0,399		Algorithm converged.	0,125	1,275	-0,484	Algorithm converged.	-1,074	0,106	0,401		Algorithm converged.	0,126	1,274	0,1783	1	2,496	Algorithm converged.	0,785	7,937	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthralgia	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthritis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Back pain	USA	1237	93,078	0	0	1239	93,018	3	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,516	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Costochondritis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk										
			Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Intervertebral disc protrusion	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm not converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Joint effusion	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Myalgia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain in extremity	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastric cancer	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Squamous cell carcinoma of skin	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	USA	1237	93,078	12	0,97	1239	93,018	11	0,888	1,094	Algorithm converged.	0,481	2,488	0,082		Algorithm converged.	-0,673	0,838	1,093		Algorithm converged.	0,484	2,467	0,8311	1	0,915		Algorithm converged.	0,405	2,066
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ageusia	USA	1237	93,078	1	0,081	1239	93,018	3	0,242	0,333	Algorithm converged.	0,035	3,209	-0,161		Algorithm converged.	-0,477	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995		Algorithm converged.	0,312	28,755
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anosmia	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081		Algorithm converged.	-0,355	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997		Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bell's palsy	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dementia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dizziness	USA	1237	93,078	2	0,162	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,162		Algorithm converged.	-0,062	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Facial paresis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk											
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	USA	1237	93,078	3	0,243	1239	93,018	4	0,323	0,751		Algorithm converged.	0,168	3,361	-0,08		Algorithm converged.	-0,499	0,338	0,751		Algorithm converged.	0,168	3,349	1	1	1,331		Algorithm converged.	0,299	5,935
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypogeusia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyposmia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Parosmia	USA	1237	93,078	2	0,162	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,162		Algorithm converged.	-0,062	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Presyncope	USA	1237	93,078	0	0	1239	93,018	3	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242		Algorithm converged.	-0,516	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Syncope	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tremor	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Pregnancy, puerperium and perinatal conditions	--		USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
Ectopic pregnancy			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Pregnancy			USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Psychiatric disorders	--		USA	1237	93,078	3	0,243	1239	93,018	3	0,242	1,002	Algorithm converged.	0,202	4,972	0	Algorithm converged.	-0,387	0,388	1,002	Algorithm converged.	0,203	4,953	1	0,2626	0,998	Algorithm converged.	0,202	4,937	
			MEX	92	6,922	1	1,087	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	1,087	Algorithm converged.	-1,032	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
Anxiety			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Depression			USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	1	1,087	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	1,087	Algorithm converged.	-1,032	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
Insomnia			USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Mental status changes			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk												
			Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,078	1	0,081	1239	93,018	3	0,242	0,333		Algorithm converged.	0,035	3,209	-0,161		Algorithm converged.	-0,477	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995		Algorithm converged.	0,312	28,755
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute kidney injury	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998		Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	USA	1237	93,078	2	0,162	1239	93,018	1	0,081	2,005		Algorithm converged.	0,182	22,139	0,081		Algorithm converged.	-0,193	0,355	2,003		Algorithm converged.	0,182	22,064	0,6245	1	0,499		Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Heavy menstrual bleeding	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Suppressed lactation	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Testicular pain	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm not converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,078	26	2,102	1239	93,018	40	3,228	0,644		Algorithm converged.	0,39	1,061	-1,127	Algorithm converged.	-2,394	0,141	0,651		Algorithm converged.	0,4	1,06	0,0819	0,7589	1,536	Algorithm converged.	0,943	2,501	
			MEX	92	6,922	1	1,087	93	6,982	1	1,075	1,011		Algorithm converged.	0,062	16,409	0,012	Algorithm converged.	-2,969	2,992	1,011		Algorithm converged.	0,064	15,92	1		0,989	Algorithm converged.	0,063	15,58	
		Acute respiratory distress syndrome	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	USA	1237	93,078	0	0	1239	93,018	4	0,323	NE	*	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,639	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Asthma	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchial secretion retention	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchospasm	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk										
			Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Chronic obstructive pulmonary disease	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cough	USA	1237	93,078	11	0,889	1239	93,018	8	0,646	1,381		Algorithm converged.	0,553	3,444	0,244	Algorithm converged.	-0,444	0,931	1,377		Algorithm converged.	0,556	3,412	0,4875	1	0,726	Algorithm converged.	0,293	1,799	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	USA	1237	93,078	7	0,566	1239	93,018	16	1,291	0,435		Algorithm converged.	0,178	1,061	-0,725	Algorithm converged.	-1,48	0,029	0,438		Algorithm converged.	0,181	1,061	0,06	0,1287	2,282	Algorithm converged.	0,942	5,528	
			MEX	92	6,922	1	1,087	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	1,087	Algorithm converged.	-1,032	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
		Dyspnoea exertional	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Epistaxis	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	1237	93,078	2	0,162	1239	93,018	6	0,484	0,333		Algorithm converged.	0,067	1,652	-0,323	Algorithm converged.	-0,769	0,124	0,334		Algorithm converged.	0,068	1,651	0,2883	1	2,995	Algorithm converged.	0,606	14,811	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nasal congestion	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oropharyngeal pain	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab																					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk																					
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL															
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
		Pneumothorax spontaneous	USA	1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	*	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
		Productive cough	USA	1237	93,078	2	0,162	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,162	*	Algorithm converged.	-0,062	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
		Pulmonary congestion	USA	1237	93,078	3	0,243	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,243	*	Algorithm converged.	-0,032	0,517	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
		Pulmonary mass	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998		Algorithm converged.	0,063	15,944										
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
		Respiratory distress	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
		Respiratory tract congestion	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
		Sinus congestion	USA	1237	93,078	0	0	1239	93,018	4	0,323	NE	*	Algorithm not converged.	NE	NE	-0,323	*	Algorithm converged.	-0,639	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Skin and subcutaneous tissue disorders	--	USA	1237	93,078	6	0,485	1239	93,018	6	0,484	1,002	Algorithm converged.	0,322	3,114	0,001	Algorithm converged.	-0,546	0,548	1,002	Algorithm converged.	0,324	3,097	0,9978	1	0,998	Algorithm converged.	0,323	3,087
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Acne		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Pruritus		USA	1237	93,078	0	0	1239	93,018	2	0,161	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Rash		USA	1237	93,078	6	0,485	1239	93,018	4	0,323	1,505	Algorithm converged.	0,424	5,346	0,162	Algorithm converged.	-0,337	0,662	1,502	Algorithm converged.	0,425	5,311	0,5477	1	0,666	Algorithm converged.	0,188	2,353
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Surgical and medical procedures	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Hospitalisation		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Vascular disorders	--	USA	1237	93,078	2	0,162	1239	93,018	5	0,404	0,4	Algorithm converged.	0,077	2,064	-0,242	Algorithm converged.	-0,66	0,176	0,401	Algorithm converged.	0,078	2,061	0,4525	1	2,496	Algorithm converged.	0,485	12,841
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
	Flushing		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab															
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk															
			Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
		Hypertension	USA	1237	93,078	1	0,081	1239	93,018	3	0,242	0,333		Algorithm converged.	0,035	3,209	-0,161		Algorithm converged.	-0,477	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995		Algorithm converged.	0,312	28,755					
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		May-Thurner syndrome	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Thrombophlebitis superficial	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	Blood and lymphatic system disorders	--	--	1329	100	6	0,451	1332	100	2	0,15	3,016	Algorithm converged.	0,608	14,969	0,301	Algorithm converged.	-0,115	0,717	3,007	Algorithm converged.	0,608	14,87	0,1786		0,333	Algorithm converged.	0,067	1,645
	Eosinophilia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Iron deficiency anaemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Leukocytosis	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Leukopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Lymphopenia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Thrombocytopenia	--	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
	Thrombocytosis	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495
	Cardiac disorders	--	--	1329	100	4	0,301	1332	100	6	0,45	0,667	Algorithm converged.	0,188	2,37	-0,149	Algorithm converged.	-0,614	0,315	0,668	Algorithm converged.	0,189	2,362	0,7534		1,497	Algorithm converged.	0,423	5,291
	Acute myocardial infarction	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Angina pectoris	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Cardiac failure congestive	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Coronary artery disease	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Palpitations	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Sinus tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Eye disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cataract	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	9	0,677	1332	100	15	1,126	0,599	Algorithm converged.	0,261	1,373	-0,449	Algorithm converged.	-1,167	0,269	0,601	Algorithm converged.	0,264	1,369	0,2208		1,663	Algorithm converged.	0,73	3,787
		Abdominal distension	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Abdominal pain	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Abdominal pain upper	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Chronic gastritis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Constipation	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Diarrhoea	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Gastric ulcer	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Gastritis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	--	1329	100	2	0,15	1332	100	2	0,15	1,002	Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002	Algorithm converged.	0,141	7,105	1		0,998	Algorithm converged.	0,141	7,073
		Nausea	--	1329	100	4	0,301	1332	100	4	0,3	1,002	Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002	Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
		Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vomiting	--	1329	100	0	0	1332	100	5	0,375	NE *	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE *	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	9	0,677	1332	100	19	1,426	0,471	Algorithm converged.	0,212	1,045	-0,749	Algorithm converged.	-1,524	0,025	0,475	Algorithm converged.	0,216	1,045	0,0583		2,106	Algorithm converged.	0,956	4,639
		Chest discomfort	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Death	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Fatigue	--	1329	100	2	0,15	1332	100	3	0,225	0,668		Algorithm converged.	0,111	4,002	-0,075	Algorithm converged.	-0,404	0,254	0,668		Algorithm converged.	0,112	3,992	1		1,497		Algorithm converged.	0,25	8,942
		Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995		Algorithm converged.	0,181	21,98
		Oedema peripheral	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Pain	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995		Algorithm converged.	0,181	21,98
		Peripheral swelling	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995		Algorithm converged.	0,181	21,98
		Pyrexia	--	1329	100	2	0,15	1332	100	6	0,45	0,333		Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334		Algorithm converged.	0,068	1,652	0,2883		2,993		Algorithm converged.	0,605	14,803
		Swelling face	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998		Algorithm converged.	0,062	15,935
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
	Immune system disorders	--	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
		Seasonal allergy	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	22	1,655	1332	100	31	2,327	0,706		Algorithm converged.	0,407	1,227	-0,672	Algorithm converged.	-1,733	0,389	0,711		Algorithm converged.	0,414	1,222	0,2149		1,406		Algorithm converged.	0,818	2,415
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Breast abscess	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Bronchitis	--	1329	100	4	0,301	1332	100	1	0,075	4,018		Algorithm converged.	0,449	35,997	0,226	Algorithm converged.	-0,103	0,555	4,009		Algorithm converged.	0,449	35,821	0,2179		0,249		Algorithm converged.	0,028	2,229
		Cellulitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Kidney infection	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995		Algorithm converged.	0,181	21,98
		Pneumonia	--	1329	100	7	0,527	1332	100	14	1,051	0,498		Algorithm converged.	0,201	1,239	-0,524	Algorithm converged.	-1,196	0,148	0,501		Algorithm converged.	0,203	1,238	0,1265		1,995		Algorithm converged.	0,808	4,928
		Pneumonia bacterial	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995		Algorithm converged.	0,181	21,98
		Pneumonia viral	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995		Algorithm converged.	0,181	21,98
		Rectal abscess	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Sinusitis	--	1329	100	4	0,301	1332	100	3	0,225	1,337		Algorithm converged.	0,299	5,987	0,076	Algorithm converged.	-0,314	0,465	1,336		Algorithm converged.	0,3	5,959	0,7259		0,748		Algorithm converged.	0,168	3,337
		Superinfection bacterial	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Tooth abscess	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Upper respiratory tract infection	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	--	1329	100	4	0,301	1332	100	1	0,075	4,018		Algorithm converged.	0,449	35,997	0,226	Algorithm converged.	-0,103	0,555	4,009		Algorithm converged.	0,449	35,821	0,2179		0,249		Algorithm converged.	0,028	2,229

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Injury, poisoning and procedural complications	--	--	1329	100	7	0,527	1332	100	1	0,075	7,048	Algorithm converged.	0,866	57,361	0,452	Algorithm converged.	0,036	0,868	7,016	Algorithm converged.	0,864	56,944	0,0386		0,143	Algorithm converged.	0,018	1,157
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Contusion	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Infusion related reaction	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Ligament sprain	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Skin laceration	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Investigations	--	--	1329	100	26	1,956	1332	100	23	1,727	1,136	Algorithm converged.	0,645	2,001	0,23	Algorithm converged.	-0,792	1,251	1,133	Algorithm converged.	0,65	1,975	0,6596		0,883	Algorithm converged.	0,506	1,539
		Activated partial thromboplastin time prolonged	--	1329	100	7	0,527	1332	100	7	0,526	1,002	Algorithm converged.	0,351	2,865	0,001	Algorithm converged.	-0,549	0,551	1,002	Algorithm converged.	0,353	2,849	0,9966		0,998	Algorithm converged.	0,351	2,837
		Alanine aminotransferase increased	--	1329	100	4	0,301	1332	100	4	0,3	1,002	Algorithm converged.	0,25	4,016	0,001	Algorithm converged.	-0,415	0,417	1,002	Algorithm converged.	0,251	3,999	1		0,998	Algorithm converged.	0,25	3,981
		Aspartate aminotransferase increased	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244		0,499	Algorithm converged.	0,045	5,495

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Bleeding time prolonged	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	--	1329	100	5	0,376	1332	100	2	0,15	2,511		Algorithm converged.	0,486	12,967	0,226	Algorithm converged.	-0,163	0,615	2,506		Algorithm converged.	0,487	12,892	0,288		0,399		Algorithm converged.	0,078	2,053
		Blood lactate dehydrogenase increased	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		C-reactive protein increased	--	1329	100	7	0,527	1332	100	7	0,526	1,002		Algorithm converged.	0,351	2,865	0,001	Algorithm converged.	-0,549	0,551	1,002		Algorithm converged.	0,353	2,849	0,9966		0,998		Algorithm converged.	0,351	2,837
		Fibrin D dimer increased	--	1329	100	7	0,527	1332	100	9	0,676	0,778		Algorithm converged.	0,289	2,096	-0,149	Algorithm converged.	-0,736	0,438	0,78		Algorithm converged.	0,291	2,087	0,6193		1,283		Algorithm converged.	0,479	3,434
		Heart rate decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Hepatic enzyme increased	--	1329	100	2	0,15	1332	100	2	0,15	1,002		Algorithm converged.	0,141	7,126	0	Algorithm converged.	-0,294	0,295	1,002		Algorithm converged.	0,141	7,105	1		0,998		Algorithm converged.	0,141	7,073
		International normalised ratio increased	--	1329	100	2	0,15	1332	100	1	0,075	2,006		Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005		Algorithm converged.	0,182	22,08	0,6244		0,499		Algorithm converged.	0,045	5,495
		Prothrombin time prolonged	--	1329	100	2	0,15	1332	100	1	0,075	2,006		Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005		Algorithm converged.	0,182	22,08	0,6244		0,499		Algorithm converged.	0,045	5,495
		Serum ferritin increased	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
		Transaminases increased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE		Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	--	1329	100	9	0,677	1332	100	13	0,976	0,692		Algorithm converged.	0,295	1,624	-0,299	Algorithm converged.	-0,987	0,389	0,694		Algorithm converged.	0,298	1,618	0,3948		1,441		Algorithm converged.	0,618	3,36
		Dehydration	--	1329	100	0	0	1332	100	6	0,45	NE	*	Algorithm not converged.	NE	NE	-0,45	Algorithm converged.	-0,81	-0,091	NE	*	Algorithm not converged.	NE	NE	0,0311		NE		Algorithm not converged.	NE	NE
		Haemochromatosis	--	1329	100	1	0,075	1332	100	3	0,225	0,334		Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334		Algorithm converged.	0,035	3,208	0,6247		2,993		Algorithm converged.	0,312	28,739
		Hyperglycaemia	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE		Algorithm not converged.	NE	NE

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Clinical cut-off: 19Aug2021

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

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				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyperkalaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Hyponatraemia	--	1329	100	2	0,15	1332	100	3	0,225	0,668		Algorithm converged.	0,111	4,002	-0,075	Algorithm converged.	-0,404	0,254	0,668		Algorithm converged.	0,112	3,992	1		1,497	Algorithm converged.	0,25	8,942
		Malnutrition	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Musculoskeletal and connective tissue disorders	--	--	1329	100	4	0,301	1332	100	10	0,751	0,399		Algorithm converged.	0,125	1,276	-0,45	Algorithm converged.	-0,999	0,099	0,401		Algorithm converged.	0,126	1,275	0,1784		2,494	Algorithm converged.	0,784	7,933
		Arthralgia	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Arthritis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Back pain	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Costochondritis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Joint effusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Myalgia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pain in extremity	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Squamous cell carcinoma of skin	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	12	0,903	1332	100	11	0,826	1,094	Algorithm converged.	0,481	2,489	0,077	Algorithm converged.	-0,626	0,781	1,093	Algorithm converged.	0,484	2,469	0,8299		0,915	Algorithm converged.	0,405	2,065
		Ageusia	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		Anosmia	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Bell's palsy	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Dementia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Dizziness	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	3	0,226	1332	100	4	0,3	0,751	Algorithm converged.	0,168	3,363	-0,075	Algorithm converged.	-0,464	0,315	0,752	Algorithm converged.	0,169	3,352	1		1,33	Algorithm converged.	0,298	5,932
		Hypogeusia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyposmia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Parosmia	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE
		Presyncope	--	1329	100	0	0	1332	100	3	0,225	NE *	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tremor	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL
	Pregnancy, puerperium and perinatal conditions	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1	0,998	Algorithm converged.	0,062	15,935
	Ectopic pregnancy	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994	NE	Algorithm not converged.	NE	NE
	Pregnancy	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	1329	100	4	0,301	1332	100	3	0,225	1,337	Algorithm converged.	0,299	5,987	0,076	Algorithm converged.	-0,314	0,465	1,336	Algorithm converged.	0,3	5,959	0,7259	0,748	Algorithm converged.	0,168	3,337
	Anxiety	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994	NE	Algorithm not converged.	NE	NE
	Depression	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1	0,998	Algorithm converged.	0,062	15,935
	Insomnia	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1	1,995	Algorithm converged.	0,181	21,98
	Mental status changes	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994	NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247	2,993	Algorithm converged.	0,312	28,739
	Acute kidney injury	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Nephrolithiasis	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1	0,998	Algorithm converged.	0,062	15,935
	Renal failure	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	--	1329	100	2	0,15	1332	100	1	0,075	2,006	Algorithm converged.	0,182	22,15	0,075	Algorithm converged.	-0,18	0,33	2,005	Algorithm converged.	0,182	22,08	0,6244	0,499	Algorithm converged.	0,045	5,495
	Heavy menstrual bleeding	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994	NE	Algorithm not converged.	NE	NE
	Suppressed lactation	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
	Testicular pain	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	27	2,032	1332	100	41	3,078	0,653	Algorithm converged.	0,399	1,068	-1,046	Algorithm converged.	-2,245	0,152	0,66	Algorithm converged.	0,408	1,066	0,0872		1,515	Algorithm converged.	0,938	2,448
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Asthma	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Bronchial secretion retention	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Bronchospasm	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cough	--	1329	100	11	0,828	1332	100	8	0,601	1,381	Algorithm converged.	0,554	3,445	0,227	Algorithm converged.	-0,413	0,867	1,378	Algorithm converged.	0,556	3,415	0,4867		0,726	Algorithm converged.	0,293	1,798
		Dyspnoea	--	1329	100	8	0,602	1332	100	16	1,201	0,498	Algorithm converged.	0,212	1,168	-0,599	Algorithm converged.	-1,317	0,119	0,501	Algorithm converged.	0,215	1,167	0,1021		1,995	Algorithm converged.	0,857	4,647
		Dyspnoea exertional	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Epistaxis	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Hypoxia	--	1329	100	2	0,15	1332	100	6	0,45	0,333	Algorithm converged.	0,067	1,653	-0,3	Algorithm converged.	-0,716	0,116	0,334	Algorithm converged.	0,068	1,652	0,2883		2,993	Algorithm converged.	0,605	14,803
		Nasal congestion	--	1329	100	1	0,075	1332	100	2	0,15	0,501	Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501	Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Oropharyngeal pain	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Productive cough	--	1329	100	2	0,15	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,15	Algorithm converged.	-0,058	0,359	NE *	Algorithm not converged.	NE	NE	0,2493		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pulmonary congestion	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Respiratory distress	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Respiratory tract congestion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sinus congestion	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Skin and subcutaneous tissue disorders	--	1329	100	6	0,451	1332	100	6	0,45	1,002		Algorithm converged.	0,322	3,116	0,001	Algorithm converged.	-0,508	0,51	1,002		Algorithm converged.	0,324	3,1	0,9969		0,998	Algorithm converged.	0,323	3,086
		Acne	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pruritus	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Rash	--	1329	100	6	0,451	1332	100	4	0,3	1,506		Algorithm converged.	0,424	5,348	0,151	Algorithm converged.	-0,314	0,616	1,503		Algorithm converged.	0,425	5,315	0,5477		0,665	Algorithm converged.	0,188	2,352
		Surgical and medical procedures	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vascular disorders	--	1329	100	2	0,15	1332	100	5	0,375	0,4		Algorithm converged.	0,077	2,065	-0,225	Algorithm converged.	-0,614	0,164	0,401		Algorithm converged.	0,078	2,063	0,4525		2,494	Algorithm converged.	0,485	12,834
		Flushing	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypertension	--	1329	100	1	0,075	1332	100	3	0,225	0,334		Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334		Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Sex	Blood and lymphatic system disorders	--	Male	641	48,232	2	0,312	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,312	Algorithm converged.	-0,12	0,744	NE	*	Algorithm not converged.	NE	NE	0,4996	0,2478	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	4	0,581	698	52,402	2	0,287	2,035		Algorithm converged.	0,372	11,147	0,295	Algorithm converged.	-0,398	0,988	2,029	Algorithm converged.	0,373	11,042	0,4489		0,493	Algorithm converged.	0,091	2,682		
	Eosinophilia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Iron deficiency anaemia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Leukocytosis		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Leukopenia		Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Lymphopenia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Thrombocytopenia		Male	641	48,232	2	0,312	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,312	Algorithm converged.	-0,12	0,744	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Thrombocytosis		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	1	0,143	2,032		Algorithm converged.	0,184	22,462	0,147	Algorithm converged.	-0,343	0,638	2,029	Algorithm converged.	0,184	22,325	0,622		0,493	Algorithm converged.	0,045	5,423		

Test for interaction based on RRR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Cardiac disorders	--	Male	641	48,232	4	0,624	634	47,598	2	0,315	1,984	Algorithm converged.	0,362	10,872	0,309	Algorithm converged.	-0,441	1,058	1,978	Algorithm converged.	0,364	10,762	0,6868	0,0164	0,506	Algorithm converged.	0,093	2,75
			Female	688	51,768	0	0	698	52,402	4	0,573	NE *	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,133	-0,013	NE *	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Angina pectoris		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989	Algorithm converged.	0,062	15,779	1	0,3101	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Palpitations		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Sinus tachycardia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Tachycardia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Eye disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Cataract	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	641	48,232	4	0,624	634	47,598	6	0,946	0,657		Algorithm converged.	0,185	2,34	-0,322		Algorithm converged.	-1,292	0,647	0,659		Algorithm converged.	0,187	2,325	0,5452	0,8535	1,517		Algorithm converged.	0,43	5,349
			Female	688	51,768	5	0,727	698	52,402	9	1,289	0,56		Algorithm converged.	0,187	1,681	-0,563		Algorithm converged.	-1,613	0,488	0,564		Algorithm converged.	0,19	1,673	0,4217		1,774		Algorithm converged.	0,598	5,267
		Abdominal distension	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Abdominal pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
		Abdominal pain upper	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Chronic gastritis	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Constipation	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986	Algorithm converged.	0,062	15,727	
		Diarrhoea	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Gastric ulcer	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastritis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,9899	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1	0,986	Algorithm converged.	0,062	15,727	
		Nausea	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,9876	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	3	0,436	698	52,402	3	0,43	1,015		Algorithm converged.	0,204	5,044	0,006	Algorithm converged.	-0,685	0,698	1,015		Algorithm converged.	0,205	5,009	1	0,986	Algorithm converged.	0,2	4,867	
		Peptic ulcer perforation	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Vomiting	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	Male	641	48,232	4	0,624	634	47,598	6	0,946	0,657		Algorithm converged.	0,185	2,34	-0,322	Algorithm converged.	-1,292	0,647	0,659		Algorithm converged.	0,187	2,325	0,5452	0,5278	1,517	Algorithm converged.	0,43	5,349	
			Female	688	51,768	5	0,727	698	52,402	13	1,862	0,386		Algorithm converged.	0,137	1,088	-1,136	Algorithm converged.	-2,323	0,051	0,39		Algorithm converged.	0,14	1,089	0,0943		2,563	Algorithm converged.	0,919	7,15	
		Chest discomfort	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Death	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Fatigue	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,1377	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	3	0,43	0,337		Algorithm converged.	0,035	3,25	-0,284	Algorithm converged.	-0,847	0,278	0,338		Algorithm converged.	0,035	3,243	0,6245		2,957	Algorithm converged.	0,308	28,358	
		Fever neonatal	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Multiple organ dysfunction syndrome	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Non-cardiac chest pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507		Algorithm converged.	0,046	5,599	-0,141		Algorithm converged.	-0,629	0,347	0,507		Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69
		Oedema peripheral	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494		Algorithm converged.	0,045	5,459	-0,159		Algorithm converged.	-0,692	0,373	0,495		Algorithm converged.	0,045	5,44	0,6227	1	2,022	Algorithm converged.	0,184	22,244
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peripheral swelling	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507		Algorithm converged.	0,046	5,599	-0,141		Algorithm converged.	-0,629	0,347	0,507		Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69
		Pyrexia	Male	641	48,232	2	0,312	634	47,598	4	0,631	0,493		Algorithm converged.	0,09	2,701	-0,319		Algorithm converged.	-1,071	0,434	0,495		Algorithm converged.	0,091	2,69	0,4497	0,2478	2,022	Algorithm converged.	0,372	11,001
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Swelling face	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hepatobiliary disorders	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hyperbilirubinaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Immune system disorders	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Seasonal allergy	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Infections and infestations	Male	641	48,232	11	1,716	634	47,598	15	2,366	0,721		Algorithm converged.	0,328	1,581	-0,65	Algorithm converged.	-2,202	0,903	0,725		Algorithm converged.	0,336	1,567	0,4119	0,9435	1,379	Algorithm converged.	0,638	2,978	
			Female	688	51,768	11	1,599	698	52,402	16	2,292	0,693		Algorithm converged.	0,319	1,503	-0,693	Algorithm converged.	-2,146	0,76	0,697		Algorithm converged.	0,326	1,492	0,3505		1,434	Algorithm converged.	0,67	3,067	
		Bacteraemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Breast abscess	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Bronchitis	Male	641	48,232	3	0,468	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,468	Algorithm converged.	-0,06	0,996	NE	*	Algorithm not converged.	NE	NE	0,2494	0,1377	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		Cellulitis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Clostridium difficile colitis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Kidney infection	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Lung abscess	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Osteomyelitis acute	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0516	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
		Pneumonia	Male	641	48,232	6	0,936	634	47,598	8	1,262	0,739		Algorithm converged.	0,255	2,143	-0,326		Algorithm converged.	-1,471	0,819	0,742		Algorithm converged.	0,259	2,126	0,5769	0,1781	1,348		Algorithm converged.	0,47	3,863
			Female	688	51,768	1	0,145	698	52,402	6	0,86	0,168		Algorithm converged.	0,02	1,398	-0,714		Algorithm converged.	-1,456	0,027	0,169		Algorithm converged.	0,02	1,401	0,1241		5,914		Algorithm converged.	0,714	48,995
		Pneumonia bacterial	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,3023	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986		Algorithm converged.	0,062	15,727

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pneumonia viral	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	0,0496	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Rectal abscess	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Sinusitis	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494		Algorithm converged.	0,045	5,459	-0,159	Algorithm converged.	-0,692	0,373	0,495		Algorithm converged.	0,045	5,44	0,6227	0,2574	2,022		Algorithm converged.	0,184	22,244
			Female	688	51,768	3	0,436	698	52,402	1	0,143	3,053		Algorithm converged.	0,317	29,418	0,293	Algorithm converged.	-0,274	0,859	3,044		Algorithm converged.	0,317	29,188	0,3709		0,329		Algorithm converged.	0,034	3,151
		Superinfection bacterial	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tooth abscess	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Upper respiratory tract infection	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	4	0,581	698	52,402	1	0,143	4,076		Algorithm converged.	0,454	36,56	0,438	Algorithm converged.	-0,195	1,072	4,058		Algorithm converged.	0,455	36,216	0,2147		0,246		Algorithm converged.	0,028	2,199

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
	Injury, poisoning and procedural complications	--	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	0,1342	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,768	5	0,727	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,727	Algorithm converged.	0,092	1,361	NE	Algorithm not converged.	NE	NE	0,0299		NE	Algorithm not converged.	NE	NE
		Ankle fracture	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Contusion	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Fall	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,291	Algorithm converged.	-0,112	0,693	NE	Algorithm not converged.	NE	NE	0,2462		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Infusion related reaction	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ligament sprain	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Odds Ratio				Absolute Risk Difference				Relative Risk					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Interaction Test p-value (likelihood ratio)	Relative Risk		Relative Risk											
				n	%	n	%	n	%	n	%	Lower CL	upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL		Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Skin laceration	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Tibia fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
Investigations	--		Male	641	48,232	14	2,184	634	47,598	13	2,05	1,067		Algorithm converged.	0,497	2,288	0,134	Algorithm converged.	-1,447	1,714	1,065		Algorithm converged.	0,505	2,248	0,8685	0,8148	0,939		Algorithm converged.	0,445	1,981
			Female	688	51,768	12	1,744	698	52,402	10	1,433	1,221		Algorithm converged.	0,524	2,846	0,312	Algorithm converged.	-1,005	1,628	1,217		Algorithm converged.	0,529	2,799	0,6428		0,821		Algorithm converged.	0,357	1,889
		Activated partial thromboplastin time prolonged	Male	641	48,232	2	0,312	634	47,598	3	0,473	0,658		Algorithm converged.	0,11	3,953	-0,161	Algorithm converged.	-0,848	0,526	0,659		Algorithm converged.	0,111	3,933	0,6853	0,5597	1,517		Algorithm converged.	0,254	9,046
			Female	688	51,768	5	0,727	698	52,402	4	0,573	1,27		Algorithm converged.	0,34	4,75	0,154	Algorithm converged.	-0,693	1	1,268		Algorithm converged.	0,342	4,703	0,7515		0,789		Algorithm converged.	0,213	2,924
		Alanine aminotransferase increased	Male	641	48,232	3	0,468	634	47,598	2	0,315	1,486		Algorithm converged.	0,247	8,923	0,153	Algorithm converged.	-0,533	0,838	1,484		Algorithm converged.	0,249	8,849	1	0,4719	0,674		Algorithm converged.	0,113	4,02
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507		Algorithm converged.	0,046	5,599	-0,141	Algorithm converged.	-0,629	0,347	0,507		Algorithm converged.	0,046	5,581	1		1,971		Algorithm converged.	0,179	21,69

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Aspartate aminotransferase increased	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,3101	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		Bleeding time prolonged	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Blood bicarbonate decreased	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Blood creatine phosphokinase increased	Male	641	48,232	5	0,78	634	47,598	2	0,315	2,484		Algorithm converged.	0,48	12,852	0,465	Algorithm converged.	-0,344	1,273	2,473		Algorithm converged.	0,482	12,698	0,4519	1	0,404	Algorithm converged.	0,079	2,077	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood lactate dehydrogenase increased	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	Male	641	48,232	3	0,468	634	47,598	5	0,789	0,592		Algorithm converged.	0,141	2,486	-0,321	Algorithm converged.	-1,189	0,547	0,593		Algorithm converged.	0,142	2,473	0,5042	0,265	1,685	Algorithm converged.	0,404	7,021	
			Female	688	51,768	4	0,581	698	52,402	2	0,287	2,035		Algorithm converged.	0,372	11,147	0,295	Algorithm converged.	-0,398	0,988	2,029		Algorithm converged.	0,373	11,042	0,4489		0,493	Algorithm converged.	0,091	2,682	
		Fibrin D dimer increased	Male	641	48,232	3	0,468	634	47,598	4	0,631	0,741		Algorithm converged.	0,165	3,322	-0,163	Algorithm converged.	-0,975	0,649	0,742		Algorithm converged.	0,167	3,301	0,7244	0,9293	1,348	Algorithm converged.	0,303	5,999	
			Female	688	51,768	4	0,581	698	52,402	5	0,716	0,811		Algorithm converged.	0,217	3,031	-0,135	Algorithm converged.	-0,98	0,71	0,812		Algorithm converged.	0,219	3,01	1		1,232	Algorithm converged.	0,332	4,569	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Heart rate decreased	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hepatic enzyme increased	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494		Algorithm converged.	0,045	5,459	-0,159	Algorithm converged.	-0,692	0,373	0,495		Algorithm converged.	0,045	5,44	0,6227	0,1855	2,022		Algorithm converged.	0,184	22,244	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		International normalised ratio increased	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981		Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978		Algorithm converged.	0,18	21,761	1	1	0,506		Algorithm converged.	0,046	5,561	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Prothrombin time prolonged	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981		Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978		Algorithm converged.	0,18	21,761	1	1	0,506		Algorithm converged.	0,046	5,561	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Serum ferritin increased	Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Transaminases increased	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	Male	641	48,232	5	0,78	634	47,598	5	0,789	0,989		Algorithm converged.	0,285	3,433	-0,009	Algorithm converged.	-0,977	0,96	0,989		Algorithm converged.	0,288	3,4	1	0,4435	1,011		Algorithm converged.	0,294	3,475	
			Female	688	51,768	4	0,581	698	52,402	8	1,146	0,504		Algorithm converged.	0,151	1,683	-0,565	Algorithm converged.	-1,538	0,408	0,507		Algorithm converged.	0,153	1,677	0,3857		1,971		Algorithm converged.	0,596	6,516	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dehydration	Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Haemochromatosis	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,192	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,291	Algorithm converged.	-0,112	0,693	NE	*	Algorithm not converged.	NE	NE	0,2462		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,2721	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	2	0,287	1,015		Algorithm converged.	0,143	7,223	0,004	Algorithm converged.	-0,561	0,569	1,015		Algorithm converged.	0,143	7,182	1		0,986	Algorithm converged.	0,139	6,978
		Malnutrition	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Musculoskeletal and connective tissue disorders	--	Male	641	48,232	1	0,156	634	47,598	3	0,473	0,329	Algorithm converged.	0,034	3,168	-0,317	Algorithm converged.	-0,933	0,298	0,33	Algorithm converged.	0,034	3,161	0,3717	0,835	3,033	Algorithm converged.	0,316	29,081		
			Female	688	51,768	3	0,436	698	52,402	7	1,003	0,432	Algorithm converged.	0,111	1,679	-0,567	Algorithm converged.	-1,455	0,321	0,435	Algorithm converged.	0,113	1,675	0,3421		2,3	Algorithm converged.	0,597	8,858		
	Arthralgia		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507	Algorithm converged.	0,046	5,599	-0,141	Algorithm converged.	-0,629	0,347	0,507	Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69		
	Arthritis		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Back pain		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	2	0,287	NE *	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
	Costochondritis		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Intervertebral disc protrusion		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Joint effusion		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal pain		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Myalgia	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Pain in extremity	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015	Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015	Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		Rhabdomyolysis	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989	Algorithm converged.	0,062	15,779	1	1	1,011	Algorithm converged.	0,063	16,129	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Gastric cancer	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Squamous cell carcinoma of skin	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Nervous system disorders	--	Male	641	48,232	2	0,312	634	47,598	5	0,789	0,394	Algorithm converged.	0,076	2,037	-0,477	Algorithm converged.	-1,289	0,336	0,396	Algorithm converged.	0,077	2,032	0,2852	0,1215	2,528	Algorithm converged.	0,492	12,98	
			Female	688	51,768	10	1,453	698	52,402	6	0,86	1,701	Algorithm converged.	0,615	4,706	0,594	Algorithm converged.	-0,533	1,72	1,691	Algorithm converged.	0,618	4,627	0,3009		0,591	Algorithm converged.	0,216	1,618	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Ageusia	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494	Algorithm converged.	0,045	5,459	-0,159	Algorithm converged.	-0,692	0,373	0,495	Algorithm converged.	0,045	5,44	0,6227	0,414	2,022	Algorithm converged.	0,184	22,244
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Anosmia	Male	641	48,232	1	0,156	634	47,598	2	0,315	0,494	Algorithm converged.	0,045	5,459	-0,159	Algorithm converged.	-0,692	0,373	0,495	Algorithm converged.	0,045	5,44	0,6227	1	2,022	Algorithm converged.	0,184	22,244
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bell's palsy	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Dementia	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dizziness	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,291	Algorithm converged.	-0,112	0,693	NE	Algorithm not converged.	NE	NE	0,2462		NE	Algorithm not converged.	NE	NE
		Facial paresis	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Headache	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973	0,2605	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	3	0,436	698	52,402	3	0,43	1,015	Algorithm converged.	0,204	5,044	0,006	Algorithm converged.	-0,685	0,698	1,015	Algorithm converged.	0,205	5,009	1		0,986	Algorithm converged.	0,2	4,867
		Hypogeusia	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Hyposmia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Parosmia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	2	0,291	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,291		Algorithm converged.	-0,112	0,693	NE	*	Algorithm not converged.	NE	NE	0,2462		NE		Algorithm not converged.	NE	NE	
		Presyncope	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315		Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Syncope	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Tremor	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
	Pregnancy, puerperium and perinatal conditions	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015	*	Algorithm converged.	0,064	16,187	1		0,986		Algorithm converged.	0,062	15,727	
		Ectopic pregnancy	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Pregnancy	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason		95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE		
	Psychiatric disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,1622	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	4	0,581	698	52,402	2	0,287	2,035		Algorithm converged.	0,372	11,147	0,295	Algorithm converged.	-0,398	0,988	2,029		Algorithm converged.	0,373	11,042	0,4489		0,493	Algorithm converged.	0,091	2,682	
		Anxiety	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Depression	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		Insomnia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,3023	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727	
		Mental status changes	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Renal and urinary disorders	Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	0,0331	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Acute kidney injury	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0943	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Renal failure	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,3101	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727
		Heavy menstrual bleeding	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Testicular pain	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	641	48,232	12	1,872	634	47,598	24	3,785	0,485		Algorithm converged.	0,24	0,978	-1,913	Algorithm converged.	-3,732	-0,095	0,495		Algorithm converged.	0,249	0,98	0,0393	0,2278	2,022	Algorithm converged.	1,02	4,008
			Female	688	51,768	15	2,18	698	52,402	17	2,436	0,893		Algorithm converged.	0,442	1,802	-0,255	Algorithm converged.	-1,836	1,325	0,895		Algorithm converged.	0,451	1,778	0,7518		1,117	Algorithm converged.	0,562	2,219
		Acute respiratory distress syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Acute respiratory failure	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315		Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
		Asthma	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986		Algorithm converged.	0,062	15,727
		Bronchial secretion retention	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Bronchospasm	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Cough	Male	641	48,232	5	0,78	634	47,598	5	0,789	0,989		Algorithm converged.	0,285	3,433	-0,009		Algorithm converged.	-0,977	0,96	0,989		Algorithm converged.	0,288	3,4	1	0,4429	1,011		Algorithm converged.	0,294	3,475
			Female	688	51,768	6	0,872	698	52,402	3	0,43	2,038		Algorithm converged.	0,508	8,182	0,442		Algorithm converged.	-0,405	1,29	2,029		Algorithm converged.	0,51	8,081	0,3389		0,493		Algorithm converged.	0,124	1,963
		Dyspnoea	Male	641	48,232	3	0,468	634	47,598	10	1,577	0,293		Algorithm converged.	0,08	1,071	-1,109		Algorithm converged.	-2,214	-0,005	0,297		Algorithm converged.	0,082	1,073	0,0549	0,2319	3,37		Algorithm converged.	0,932	12,188
			Female	688	51,768	5	0,727	698	52,402	6	0,86	0,844		Algorithm converged.	0,256	2,78	-0,133		Algorithm converged.	-1,067	0,801	0,845		Algorithm converged.	0,259	2,757	1		1,183		Algorithm converged.	0,363	3,858

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dyspnoea exertional	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Epistaxis	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	1	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	Male	641	48,232	1	0,156	634	47,598	6	0,946	0,164	Algorithm converged.	0,02	1,362	-0,79		Algorithm converged.	-1,604	0,023	0,165		Algorithm converged.	0,02	1,365	0,0682	0,0694	6,066		Algorithm converged.	0,732	50,244
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Nasal congestion	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,3101	1,011		Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Oropharyngeal pain	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Productive cough	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Pulmonary congestion	Male	641	48,232	2	0,312	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,312		Algorithm converged.	-0,12	0,744	NE	*	Algorithm not converged.	NE	NE	0,4996	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pulmonary mass	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989	Algorithm converged.	0,062	15,779	1	1	1,011	Algorithm converged.	0,063	16,129	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Respiratory distress	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Respiratory tract congestion	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Sinus congestion	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE *	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
		Skin and subcutaneous tissue disorders	--	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	0,5132	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,768	4	0,581	698	52,402	5	0,716	0,811	Algorithm converged.	0,217	3,031	-0,135	Algorithm converged.	-0,98	0,71	0,812	Algorithm converged.	0,219	3,01	1		1,232	Algorithm converged.	0,332	4,569	
		Acne	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Pruritus	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Rash	Male	641	48,232	2	0,312	634	47,598	1	0,158	1,981	Algorithm converged.	0,179	21,904	0,154	Algorithm converged.	-0,377	0,685	1,978	Algorithm converged.	0,18	21,761	1	0,7902	0,506	Algorithm converged.	0,046	5,561	

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Female	688	51,768	4	0,581	698	52,402	3	0,43	1,355	Algorithm converged.	0,302	6,076	0,152	Algorithm converged.	-0,596	0,899	1,353	Algorithm converged.	0,304	6,022	0,724		0,739	Algorithm converged.	0,166	3,291
	Surgical and medical procedures	--	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	Male	641	48,232	0	0	634	47,598	2	0,315	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	Algorithm not converged.	NE	NE	0,2471	0,1953	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	2	0,291	698	52,402	3	0,43	0,675	Algorithm converged.	0,113	4,055	-0,139	Algorithm converged.	-0,769	0,491	0,676	Algorithm converged.	0,113	4,035	1		1,479	Algorithm converged.	0,248	8,821
		Flushing	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Hypertension	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	3	0,43	0,337	Algorithm converged.	0,035	3,25	-0,284	Algorithm converged.	-0,847	0,278	0,338	Algorithm converged.	0,035	3,243	0,6245		2,957	Algorithm converged.	0,308	28,358
		May-Thurner syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Age	Blood and lymphatic system disorders	--	18-64	1168	87,886	4	0,342	1183	88,814	1	0,085	4,062	Algorithm converged.	0,453	36,395	0,258	Algorithm converged.	-0,116	0,632	4,051	Algorithm converged.	0,454	36,193	0,2154	0,0972	0,247	Algorithm converged.	0,028	2,205		
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE	
	Eosinophilia		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE	
	Iron deficiency anaemia		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Leukocytosis		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Leukopenia		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Lymphopenia		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	
		Thrombocytopenia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombocytosis	18-64	1168	87,886	2	0,171	1183	88,814	1	0,085	2,027		Algorithm converged.	0,184	22,39	0,087		Algorithm converged.	-0,203	0,376	2,026		Algorithm converged.	0,184	22,309	0,6225		0,494		Algorithm converged.	0,045	5,437
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Cardiac disorders	--	18-64	1168	87,886	3	0,257	1183	88,814	3	0,254	1,013		Algorithm converged.	0,204	5,029	0,003		Algorithm converged.	-0,405	0,411	1,013		Algorithm converged.	0,205	5,008	1	0,4606	0,987		Algorithm converged.	0,2	4,882
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	2	5,714	0,33		Algorithm converged.	0,029	3,788	-3,754		Algorithm converged.	-12,333	4,826	0,343		Algorithm converged.	0,032	3,64	0,564		2,914		Algorithm converged.	0,275	30,914
		Acute myocardial infarction	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Angina pectoris	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Arrhythmia neonatal	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68		Algorithm converged.	0,041	11,248	-0,896		Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1		1,457		Algorithm converged.	0,094	22,527
		Cardiac failure congestive	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Coronary artery disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Palpitations	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sinus tachycardia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo									Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Tachycardia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	NE	NE	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Eye disorders	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	NE	NE	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE
		Cataract	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	NE	NE	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE
		Gastrointestinal disorders	18-64	1168	87,886	9	0,771	1183	88,814	10	0,845	0,911	Algorithm converged.	0,369	2,25	-0,075	Algorithm converged.	-0,798	0,649	0,912	Algorithm converged.	0,372	2,235	0,8396	0,0464	1,097	Algorithm converged.	0,447	2,69		
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE	*	Algorithm not converged.	NE	NE	-2,632	Algorithm converged.	-5,57	0,307	NE	*	Algorithm not converged.	NE	NE	0,2469	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628	NE	Algorithm not converged.	NE	NE	
		Abdominal distension	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Abdominal pain	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
	Abdominal pain upper		18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Chronic gastritis		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Constipation		18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Diarrhoea		18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
	Gastric ulcer		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastritis		18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroesophageal reflux disease	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013		Algorithm converged.	0,142	7,202	0,002		Algorithm converged.	-0,331	0,335	1,013		Algorithm converged.	0,143	7,178	1		0,987		Algorithm converged.	0,139	6,997
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nausea	18-64	1168	87,886	4	0,342	1183	88,814	2	0,169	2,029		Algorithm converged.	0,371	11,1	0,173		Algorithm converged.	-0,235	0,582	2,026		Algorithm converged.	0,372	11,038	0,4497	0,1803	0,494		Algorithm converged.	0,091	2,69
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754		Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Vomiting	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754		Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		General disorders and administration site conditions	18-64	1168	87,886	8	0,685	1183	88,814	13	1,099	0,621		Algorithm converged.	0,256	1,503	-0,414		Algorithm converged.	-1,173	0,345	0,623		Algorithm converged.	0,259	1,498	0,2862	0,1601	1,604		Algorithm converged.	0,667	3,856
			65-74	110	8,277	1	0,909	114	8,559	3	2,632	0,339		Algorithm converged.	0,035	3,314	-1,722		Algorithm converged.	-5,155	1,71	0,345		Algorithm converged.	0,036	3,271	0,6219		2,895		Algorithm converged.	0,306	27,409

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,846	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE
		Chest discomfort	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Fatigue	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013		Algorithm converged.	0,142	7,202	0,002	Algorithm converged.	-0,331	0,335	1,013		Algorithm converged.	0,143	7,178	1		0,987	Algorithm converged.	0,139	6,997
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Non-cardiac chest pain	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5965	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oedema peripheral	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5965	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peripheral swelling	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	18-64	1168	87,886	2	0,171	1183	88,814	6	0,507	0,336	Algorithm converged.	0,068	1,671	-0,336	Algorithm converged.	-0,805	0,133	0,338	Algorithm converged.	0,068	1,669	0,2883		2,962	Algorithm converged.	0,599	14,645
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Swelling face	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Immune system disorders	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Seasonal allergy	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Infections and infestations	18-64	1168	87,886	16	1,37	1183	88,814	26	2,198	0,618		Algorithm converged.	0,33	1,158	-0,828		Algorithm converged.	-1,897	0,241	0,623		Algorithm converged.	0,336	1,156	0,1298	0,2253	1,604	Algorithm converged.	0,865	2,975

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			65-74	110	8,277	4	3,636	114	8,559	5	4,386	0,823	Algorithm converged.	0,215	3,147	-0,75	Algorithm converged.	-5,885	4,385	0,829	Algorithm converged.	0,229	3,007	1		1,206	Algorithm converged.	0,333	4,375
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE	Algorithm not converged.	NE	NE	3,922	Algorithm converged.	-1,406	9,249	NE	Algorithm not converged.	NE	NE	0,5116		NE	Algorithm not converged.	NE	NE
		Bacteraemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Breast abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchitis	18-64	1168	87,886	3	0,257	1183	88,814	0	0	NE	Algorithm not converged.	NE	NE	0,257	Algorithm converged.	-0,033	0,547	NE	Algorithm not converged.	NE	NE	0,1225		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037	Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036	Algorithm converged.	0,066	16,365	1		0,965	Algorithm converged.	0,061	15,236
			>=75	51	3,837	0	0	35	2,628	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cellulitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Gastroenteritis	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
		Kidney infection	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
		Lung abscess	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
		Osteomyelitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
		Pharyngitis streptococcal	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747			
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		NE	Algorithm not converged.	NE	NE	
		Pneumonia	18-64	1168	87,886	3	0,257	1183	88,814	12	1,014	0,251		Algorithm converged.	0,071	0,893	-0,758	Algorithm converged.	-1,398	-0,117	0,253	Algorithm converged.	0,072	0,895	0,0346	0,0701	3,949	Algorithm converged.	1,117	13,959			
			65-74	110	8,277	2	1,818	114	8,559	2	1,754	1,037		Algorithm converged.	0,144	7,494	0,064	Algorithm converged.	-3,406	3,534	1,036	Algorithm converged.	0,149	7,229	1		0,965	Algorithm converged.	0,138	6,731			

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	3,922	Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5965	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rectal abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinusitis	18-64	1168	87,886	3	0,257	1183	88,814	2	0,169	1,521		Algorithm converged.	0,254	9,117	0,088	Algorithm converged.	-0,285	0,461	1,519		Algorithm converged.	0,254	9,076	0,6853	0,9743	0,658	Algorithm converged.	0,11	3,932
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037		Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036		Algorithm converged.	0,066	16,365	1		0,965	Algorithm converged.	0,061	15,236
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Superinfection bacterial	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tooth abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper respiratory tract infection	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Urinary tract infection	18-64	1168	87,886	3	0,257	1183	88,814	1	0,085	3,044		Algorithm converged.	0,316	29,304	0,172		Algorithm converged.	-0,162	0,507	3,039		Algorithm converged.	0,317	29,169	0,3715		0,329		Algorithm converged.	0,034	3,159
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Injury, poisoning and procedural complications	18-64	1168	87,886	2	0,171	1183	88,814	1	0,085	2,027		Algorithm converged.	0,184	22,39	0,087		Algorithm converged.	-0,203	0,376	2,026		Algorithm converged.	0,184	22,309	0,6225	0,3566	0,494		Algorithm converged.	0,045	5,437
			65-74	110	8,277	3	2,727	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	2,727		Algorithm converged.	-0,316	5,771	NE	*	Algorithm not converged.	NE	NE	0,1168		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	3,922		Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE		Algorithm not converged.	NE	NE
		Ankle fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Cervical vertebral fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		Contusion	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		Fall	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171		Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		Gastrointestinal anastomotic stenosis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		Infusion related reaction	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
		Ligament sprain	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm not converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Skin laceration	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Spinal compression fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Tibia fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	18-64	1168	87,886	23	1,969	1183	88,814	21	1,775	1,111		Algorithm converged.	0,612	2,02	0,194	Algorithm converged.	-0,902	1,29	1,109		Algorithm converged.	0,617	1,993	0,7286	0,8219	0,901	Algorithm converged.	0,502	1,62	
			65-74	110	8,277	2	1,818	114	8,559	1	0,877	2,093		Algorithm converged.	0,187	23,413	0,941	Algorithm converged.	-2,086	3,968	2,073		Algorithm converged.	0,191	22,533	0,6167		0,482	Algorithm converged.	0,044	5,245	
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68		Algorithm converged.	0,041	11,248	-0,896	Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1		1,457	Algorithm converged.	0,094	22,527	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Activated partial thromboplastin time prolonged	18-64	1168	87,886	7	0,599	1183	88,814	7	0,592	1,013	Algorithm converged.	0,354	2,897	0,008	Algorithm converged.	-0,614	0,63	1,013	Algorithm converged.	0,356	2,879	0,9809		0,987	Algorithm converged.	0,347	2,806
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	18-64	1168	87,886	3	0,257	1183	88,814	4	0,338	0,759	Algorithm converged.	0,17	3,399	-0,081	Algorithm converged.	-0,521	0,359	0,76	Algorithm converged.	0,17	3,387	1	0,4589	1,316	Algorithm converged.	0,295	5,869
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,5874	0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bleeding time prolonged	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Blood creatine phosphokinase increased	18-64	1168	87,886	4	0,342	1183	88,814	2	0,169	2,029	Algorithm converged.	0,371	11,1	0,173	Algorithm converged.	-0,235	0,582	2,026	Algorithm converged.	0,372	11,038	0,4497	0,6864	0,494	Algorithm converged.	0,091	2,69
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		Blood lactate dehydrogenase increased	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE
		C-reactive protein increased	18-64	1168	87,886	6	0,514	1183	88,814	6	0,507	1,013	Algorithm converged.	0,326	3,15	0,007	Algorithm converged.	-0,57	0,583	1,013	Algorithm converged.	0,328	3,131	0,9823	0,1977	0,987	Algorithm converged.	0,319	3,052
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407	NE	NE	NE	NE	NE
		Fibrin D dimer increased	18-64	1168	87,886	6	0,514	1183	88,814	7	0,592	0,867	Algorithm converged.	0,291	2,589	-0,078	Algorithm converged.	-0,677	0,521	0,868	Algorithm converged.	0,293	2,575	0,7987	0,4472	1,152	Algorithm converged.	0,388	3,417
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037	Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036	Algorithm converged.	0,066	16,365	1	0,965	0,061	Algorithm converged.	0,061	15,236
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407	NE	NE	NE	NE	NE
		Heart rate decreased	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013	Algorithm converged.	0,142	7,202	0,002	Algorithm converged.	-0,331	0,335	1,013	Algorithm converged.	0,143	7,178	1	0,987	0,139	Algorithm converged.	0,139	6,997

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		International normalised ratio increased	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5874	0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Prothrombin time prolonged	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5874	0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Serum ferritin increased	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Transaminases increased	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Metabolism and nutrition disorders	--		18-64	1168	87,886	8	0,685	1183	88,814	6	0,507	1,353	Algorithm converged.	0,468	3,911	0,178	Algorithm converged.	-0,445	0,8	1,35	Algorithm converged.	0,47	3,88	0,5755	0,0505	0,74	Algorithm converged.	0,258	2,128	
			65-74	110	8,277	1	0,909	114	8,559	5	4,386	0,2	Algorithm converged.	0,023	1,74	-3,477	Algorithm converged.	-7,633	0,68	0,207	Algorithm converged.	0,025	1,746	0,2129		4,825	Algorithm converged.	0,573	40,638	
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628	NE	Algorithm not converged.	NE	NE
Dehydration			18-64	1168	87,886	0	0	1183	88,814	4	0,338	NE	*	Algorithm not converged.	NE	NE	-0,338	Algorithm converged.	-0,669	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE
Haemochromatosis			18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,174	1	0,3794	0,987	Algorithm converged.	0,062	15,766	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407	NE	Algorithm not converged.	NE	NE
Hyperglycaemia			18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Hyperkalaemia			18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Hypokalaemia			18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo					Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab																
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk																	
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
		Hyponatraemia	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	*	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE	*	Algorithm not converged.	NE	NE	-2,632	*	Algorithm converged.	-5,57	0,307	NE	*	Algorithm not converged.	NE	NE	0,2469		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Malnutrition	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Type 2 diabetes mellitus	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Musculoskeletal and connective tissue disorders	18-64	1168	87,886	4	0,342	1183	88,814	9	0,761	0,448		Algorithm converged.	0,138	1,46	-0,418		Algorithm converged.	-1,016	0,18	0,45		Algorithm converged.	0,139	1,458	0,2656		2,221		Algorithm converged.	0,686	7,194					
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Arthralgia	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083		Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975		Algorithm converged.	0,179	21,747					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Arthritis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Back pain	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Costochondritis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Joint effusion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
		Myalgia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Pain in extremity	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Rhabdomyolysis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Gastric cancer	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Squamous cell carcinoma of skin	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nervous system disorders	--	18-64	1168	87,886	9	0,771	1183	88,814	11	0,93	0,827	Algorithm converged.	0,342	2,004	-0,159	Algorithm converged.	-0,901	0,583	0,829		Algorithm converged.	0,345	1,992	0,6742	0,1319	1,207	Algorithm converged.	0,502	2,901	
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Ageusia	18-64	1168	87,886	1	0,086	1183	88,814	3	0,254	0,337	Algorithm converged.	0,035	3,245	-0,168	Algorithm converged.	-0,5	0,164	0,338		Algorithm converged.	0,035	3,241	0,6247		2,962	Algorithm converged.	0,309	28,434		
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anosmia	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747		
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bell's palsy	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dementia	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Dizziness	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Facial paresis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Headache	18-64	1168	87,886	3	0,257	1183	88,814	4	0,338	0,759		Algorithm converged.	0,17	3,399	-0,081	Algorithm converged.	-0,521	0,359	0,76		Algorithm converged.	0,17	3,387	1		1,316	Algorithm converged.	0,295	5,869	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypogeusia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyposmia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Parosmia	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Presyncope	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254		Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Syncope	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tremor	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ectopic pregnancy	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,3794	0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Acute kidney injury	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,5874	0,987		Algorithm converged.	0,062	15,766
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Heavy menstrual bleeding	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Testicular pain	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	1168	87,886	22	1,884	1183	88,814	30	2,536	0,738		Algorithm converged.	0,423	1,287	-0,652	Algorithm converged.	-1,84	0,535	0,743		Algorithm converged.	0,431	1,28	0,2823	0,0536	1,346	Algorithm converged.	0,781	2,32	
			65-74	110	8,277	4	3,636	114	8,559	4	3,509	1,038		Algorithm converged.	0,253	4,256	0,128	Algorithm converged.	-4,735	4,99	1,036		Algorithm converged.	0,266	4,042	1		0,965	Algorithm converged.	0,247	3,763	
			>=75	51	3,837	1	1,961	35	2,628	7	20	0,08		Algorithm converged.	0,009	0,684	-18,039	Algorithm converged.	-31,826	-4,252	0,098		Algorithm converged.	0,013	0,762	0,0069		10,2	Algorithm converged.	1,312	79,284	
		Acute respiratory distress syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Acute respiratory failure	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Asthma	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchial secretion retention	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchospasm	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Cough	18-64	1168	87,886	11	0,942	1183	88,814	6	0,507	1,865		Algorithm converged.	0,687	5,06	0,435	Algorithm converged.	-0,251	1,121	1,857		Algorithm converged.	0,689	5,004	0,2138	0,1178	0,539	Algorithm converged.	0,2	1,451

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm not converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm not converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Dyspnoea	18-64	1168	87,886	7	0,599	1183	88,814	11	0,93	0,642		Algorithm converged.	0,248	1,663	-0,331	Algorithm converged.	-1,034	0,373	0,645		Algorithm converged.	0,251	1,657	0,358	0,0807	1,552	Algorithm converged.	0,604	3,988	
			65-74	110	8,277	1	0,909	114	8,559	1	0,877	1,037		Algorithm converged.	0,064	16,782	0,032	Algorithm converged.	-2,433	2,497	1,036		Algorithm converged.	0,066	16,365	1		0,965	Algorithm converged.	0,061	15,236	
			>=75	51	3,837	0	0	35	2,628	4	11,429	NE	*	Algorithm not converged.	NE	NE	-11,429	Algorithm converged.	-21,969	-0,888	NE	*	Algorithm not converged.	NE	NE	0,0247		NE	Algorithm not converged.	NE	NE	
		Dyspnoea exertional	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Epistaxis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	1168	87,886	2	0,171	1183	88,814	5	0,423	0,404		Algorithm converged.	0,078	2,087	-0,251	Algorithm converged.	-0,691	0,188	0,405		Algorithm converged.	0,079	2,084	0,4525	0,7366	2,468	Algorithm converged.	0,48	12,697	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nasal congestion	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506		Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506		Algorithm converged.	0,046	5,577	1		1,975	Algorithm converged.	0,179	21,747	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Oropharyngeal pain	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	*	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Productive cough	18-64	1168	87,886	2	0,171	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,171	*	Algorithm converged.	-0,066	0,408	NE	*	Algorithm not converged.	NE	NE	0,2467		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary congestion	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	*	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68	*	Algorithm converged.	0,041	11,248	-0,896	*	Algorithm converged.	-7,6	5,808	0,686	*	Algorithm converged.	0,044	10,609	1		1,457	Algorithm converged.	0,094	22,527
		Respiratory distress	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL							
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Respiratory tract congestion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Sinus congestion	18-64	1168	87,886	0	0	1183	88,814	4	0,338	NE	*	Algorithm not converged.	NE	NE	-0,338	Algorithm converged.	-0,669	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Skin and subcutaneous tissue disorders	18-64	1168	87,886	4	0,342	1183	88,814	5	0,423	0,81		Algorithm converged.	0,217	3,023	-0,08	Algorithm converged.	-0,579	0,419	0,81		Algorithm converged.	0,218	3,01	1	0,0918	1,234	Algorithm converged.	0,332	4,584					
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE	*	Algorithm not converged.	NE	NE	0,24		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Acne	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Pruritus	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Rash	18-64	1168	87,886	4	0,342	1183	88,814	3	0,254	1,352	Algorithm converged.	0,302	6,052	0,089	Algorithm converged.	-0,352	0,53	1,35	Algorithm converged.	0,303	6,021	0,7245	0,1069	0,74	Algorithm converged.	0,166	3,301
			65-74	110	8,277	2	1,818	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	1,818	Algorithm converged.	-0,679	4,315	NE *	Algorithm not converged.	NE	NE	0,24	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407	NE	NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hospitalisation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	18-64	1168	87,886	2	0,171	1183	88,814	4	0,338	0,506	Algorithm converged.	0,092	2,766	-0,167	Algorithm converged.	-0,574	0,24	0,506	Algorithm converged.	0,093	2,76	0,6871	NE	1,975	Algorithm converged.	0,362	10,76
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407	NE	NE	Algorithm not converged.	NE	NE
		Flushing	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hypertension	18-64	1168	87,886	1	0,086	1183	88,814	3	0,254	0,337	Algorithm converged.	0,035	3,245	-0,168	Algorithm converged.	-0,5	0,164	0,338	Algorithm converged.	0,035	3,241	0,6247	NE	2,962	Algorithm converged.	0,309	28,434
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		May-Thurner syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombophlebitis superficial	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Baseline viral load categories	Blood and lymphatic system disorders	--	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951	Algorithm converged.	0,176	21,612	0,263	Algorithm converged.	-0,661	1,187	1,946	Algorithm converged.	0,177	21,366	1	0,1689	0,514	Algorithm converged.	0,047	5,642
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE *	Algorithm not converged.	NE	NE	0,4618	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,508	Algorithm converged.	-0,065	1,082	NE *	Algorithm not converged.	NE	NE	0,2498	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Eosinophilia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Iron deficiency anaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Leukocytosis	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE *	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Leukopenia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Lymphopenia	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Thrombocytopenia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Thrombocytosis	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008		Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1		1,028	Algorithm converged.	0,065	16,369	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637		Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
	Cardiac disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37		Algorithm converged.	0,038	3,588	-0,917		Algorithm converged.	-2,877	1,043	0,373		Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52	
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	2	0,357	1,428		Algorithm converged.	0,238	8,581	0,152		Algorithm converged.	-0,605	0,909	1,426		Algorithm converged.	0,239	8,504	1		0,701	Algorithm converged.	0,118	4,18	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Acute myocardial infarction	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Angina pectoris	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Arrhythmia neonatal	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Atrial fibrillation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052		Algorithm converged.	0,066	16,773	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cardiac failure congestive	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Coronary artery disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Palpitations	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Sinus tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm not converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Eye disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cataract	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	2	0,556	0,973	Algorithm converged.	0,136	6,944	-0,015	Algorithm converged.	-1,086	1,056	0,973	Algorithm converged.	0,138	6,87	1	0,4899	1,028	Algorithm converged.	0,146	7,257		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	4	2,186	0,287	Algorithm converged.	0,032	2,594	-1,549	Algorithm converged.	-4,006	0,908	0,291	Algorithm converged.	0,033	2,58	0,3787	3,432	Algorithm converged.	0,388	30,385			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	5	0,847	561	42,117	7	1,248	0,676	Algorithm converged.	0,213	2,144	-0,4	Algorithm converged.	-1,58	0,779	0,679	Algorithm converged.	0,217	2,127	0,5707	1,472	Algorithm converged.	0,47	4,612			
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,193	10,09	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Abdominal distension		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Abdominal pain		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm not converged.	NE	NE	0,171	0,4874	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Abdominal pain upper	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	NE	*	Algorithm not converged.	NE	NE	0,266	0,4932	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	NE	*	Algorithm not converged.	NE	NE	0,522	1	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Chronic gastritis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	NE	*	Algorithm not converged.	NE	NE	1,881	0,4618	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Constipation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Diarrhoea	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE *	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE *	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE *	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Gastric ulcer	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Gastritis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Gastroesophageal reflux disease	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052		Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Nausea	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008		Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1		0,4442	1,028		Algorithm converged.	0,065	16,369
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905		Algorithm converged.	0,172	21,065	0,161		Algorithm converged.	-0,424	0,745	1,902		Algorithm converged.	0,173	20,914	1		0,526		Algorithm converged.	0,048	5,783	
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	3,448		Algorithm converged.	-3,193	10,09	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Vomiting	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10^5 copies/mL	370	27,84	3	0,811	360	27,027	3	0,833	0,973		Algorithm converged.	0,195	4,852	-0,023	Algorithm converged.	-1,333	1,288	0,973		Algorithm converged.	0,198	4,789	1	0,0739	1,028	Algorithm converged.	0,209	5,059	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	3	1,639	NE	*	Algorithm not converged.	NE	NE	-1,639	Algorithm converged.	-3,479	0,2	NE	*	Algorithm not converged.	NE	NE	0,2522		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	5	2,439	NE	*	Algorithm not converged.	NE	NE	-2,439	Algorithm converged.	-4,551	-0,327	NE	*	Algorithm not converged.	NE	NE	0,0629		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	6	1,017	561	42,117	8	1,426	0,71		Algorithm converged.	0,245	2,06	-0,409	Algorithm converged.	-1,681	0,863	0,713		Algorithm converged.	0,249	2,042	0,527	1,402	Algorithm converged.	0,49	4,016		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chest discomfort	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Death	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fatigue	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951		Algorithm converged.	0,176	21,612	0,263		Algorithm converged.	-0,661	1,187	1,946		Algorithm converged.	0,177	21,366	1		0,514		Algorithm converged.	0,047	5,642
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fever neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm not converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008		Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1		1,028		Algorithm converged.	0,065	16,369
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Oedema peripheral	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pain	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Peripheral swelling	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Pyrexia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,5689	NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	3	0,535	0,633		Algorithm converged.	0,105	3,8	-0,196		Algorithm converged.	-0,96	0,569	0,634		Algorithm converged.	0,106	3,779	0,6794		1,578	Algorithm converged.	0,265	9,406	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Swelling face	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
	Hepatobiliary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
	Hyperbilirubinaemia		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Immune system disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Seasonal allergy	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	8	2,222	0,239		Algorithm converged.	0,05	1,134	-1,682		Algorithm converged.	-3,378	0,014	0,243		Algorithm converged.	0,052	1,138	0,0604	0,0231	4,111		Algorithm converged.	0,879	19,228
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	7	4,459	183	13,739	2	1,093	4,223		Algorithm converged.	0,864	20,634	3,366		Algorithm converged.	-0,197	6,928	4,08		Algorithm converged.	0,86	19,355	0,0866		0,245		Algorithm converged.	0,052	1,163
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	2	1,093	205	15,39	7	3,415	0,313		Algorithm converged.	0,064	1,524	-2,322		Algorithm converged.	-5,228	0,585	0,32		Algorithm converged.	0,067	1,521	0,181		3,124		Algorithm converged.	0,657	14,85
			>10^7 copies/mL	590	44,394	11	1,864	561	42,117	14	2,496	0,742		Algorithm converged.	0,334	1,649	-0,631		Algorithm converged.	-2,322	1,059	0,747		Algorithm converged.	0,342	1,632	0,463		1,339		Algorithm converged.	0,613	2,923
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Bacteraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Breast abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	2	1,274	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	1,274		Algorithm converged.	-0,48	3,028	NE	*	Algorithm not converged.	NE	NE	0,2125		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cellulitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Kidney infection	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Lung abscess	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Osteomyelitis acute	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637		Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618	NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003	NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	3	0,833	NE	*	Algorithm not converged.	NE	NE	-0,833		Algorithm converged.	-1,772	0,106	NE	*	Algorithm not converged.	NE	NE	0,1194	0,2308	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	2	1,274	183	13,739	1	0,546	2,348		Algorithm converged.	0,211	26,147	0,727		Algorithm converged.	-1,326	2,781	2,331		Algorithm converged.	0,213	25,466	0,5973		0,429	Algorithm converged.	0,039	4,686
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37		Algorithm converged.	0,038	3,588	-0,917		Algorithm converged.	-2,877	1,043	0,373		Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	7	1,248	0,54		Algorithm converged.	0,157	1,856	-0,57		Algorithm converged.	-1,702	0,563	0,543		Algorithm converged.	0,16	1,846	0,3749		1,84	Algorithm converged.	0,542	6,253
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637		Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rectal abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637		Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sinusitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	0,3849	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	1	0,546	1,167		Algorithm converged.	0,072	18,806	0,09		Algorithm converged.	-1,549	1,73	1,166		Algorithm converged.	0,074	18,483	1		0,858		Algorithm converged.	0,054	13,604
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905		Algorithm converged.	0,172	21,065	0,161		Algorithm converged.	-0,424	0,745	1,902		Algorithm converged.	0,173	20,914	1		0,526		Algorithm converged.	0,048	5,783
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Superinfection bacterial			<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Tooth abscess			<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Upper respiratory tract infection			<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Urinary tract infection			<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	1	0,178	2,862	Algorithm converged.	0,297	27,596	0,33	Algorithm converged.	-0,342	1,002	2,853	Algorithm converged.	0,298	27,342	0,6248	0,351	Algorithm converged.	0,037	3,36	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973	Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973	Algorithm converged.	0,061	15,496	1		1,028	Algorithm converged.	0,065	16,369	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	2	1,093	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	1,093	Algorithm converged.	-0,413	2,599	NE	*	Algorithm not converged.	NE	NE	0,2218	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	4	0,678	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,678	Algorithm converged.	0,016	1,34	NE	*	Algorithm not converged.	NE	NE	0,1248	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Ankle fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Cervical vertebral fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab																			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL										
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Contusion	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Fall	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Gastrointestinal anastomotic stenosis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infusion related reaction	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm not converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Skin laceration	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Spinal compression fracture	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm not converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Tibia fracture	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Upper limb fracture	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	NE	
Investigations	--		<=10 ⁵ copies/mL	370	27,84	12	3,243	360	27,027	4	1,111	2,983		Algorithm converged.	0,953	9,338	2,132		Algorithm converged.	0,027	4,237	2,919		Algorithm converged.	0,95	8,966	0,0741	0,0041	0,343		Algorithm converged.	0,112	1,052
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	5	2,732	0,228		Algorithm converged.	0,026	1,974	-2,095		Algorithm converged.	-4,765	0,574	0,233		Algorithm converged.	0,028	1,974	0,2229		4,29		Algorithm converged.	0,507	36,329
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	2	1,093	205	15,39	9	4,39	0,241		Algorithm converged.	0,051	1,129	-3,297		Algorithm converged.	-6,481	-0,114	0,249		Algorithm converged.	0,054	1,137	0,0663		4,017		Algorithm converged.	0,879	18,351
			>10 ⁷ copies/mL	590	44,394	11	1,864	561	42,117	4	0,713	2,646		Algorithm converged.	0,837	8,357	1,151		Algorithm converged.	-0,143	2,446	2,615		Algorithm converged.	0,838	8,164	0,1178		0,382		Algorithm converged.	0,122	1,194
			Unknown	29	2,182	0	0	23	1,727	1	4,348	NE	*	Algorithm not converged.	NE	NE	-4,348		Algorithm converged.	-12,68	3,986	NE	*	Algorithm not converged.	NE	NE	0,4423		NE		Algorithm not converged.	NE	NE
		Activated partial thromboplastin time prolonged	<=10 ⁵ copies/mL	370	27,84	5	1,351	360	27,027	1	0,278	4,918		Algorithm converged.	0,572	42,302	1,074		Algorithm converged.	-0,222	2,37	4,865		Algorithm converged.	0,571	41,437	0,2171	0,0437	0,206		Algorithm converged.	0,024	1,751
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463		Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905		Algorithm converged.	0,172	21,065	0,161		Algorithm converged.	-0,424	0,745	1,902		Algorithm converged.	0,173	20,914	1		0,526		Algorithm converged.	0,048	5,783
			Unknown	29	2,182	0	0	23	1,727	1	4,348	NE	*	Algorithm not converged.	NE	NE	-4,348		Algorithm converged.	-12,68	3,986	NE	*	Algorithm not converged.	NE	NE	0,4423		NE		Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541		Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,2403	NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	2	1,093	0,58		Algorithm converged.	0,052	6,459	-0,456		Algorithm converged.	-2,41	1,498	0,583		Algorithm converged.	0,053	6,367	1		1,716		Algorithm converged.	0,157	18,744

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1			1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Aspartate aminotransferase increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm converged.	NE	NE	0,4874			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Bleeding time prolonged	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	1	4,348	NE	*	Algorithm not converged.	NE	NE	-4,348		Algorithm converged.	-12,68	3,986	NE	*	Algorithm not converged.	NE	NE	0,4423		NE		Algorithm not converged.	NE	NE	NE
		Blood creatine phosphokinase increased	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE	*	Algorithm not converged.	NE	NE	-1,093		Algorithm converged.	-2,599	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,678		Algorithm converged.	0,016	1,34	NE	*	Algorithm not converged.	NE	NE	0,1248		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Blood lactate dehydrogenase increased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		C-reactive protein increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951		Algorithm converged.	0,176	21,612	0,263		Algorithm converged.	-0,661	1,187	1,946		Algorithm converged.	0,177	21,366	1	0,1746	0,514		Algorithm converged.	0,047	5,642	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	4	1,951	0,276	Algorithm converged.	0,031	2,493	-1,405	Algorithm converged.	-3,579	0,769	0,28	Algorithm converged.	0,032	2,483	0,3758			3,571	Algorithm converged.	0,403	31,658
			>10 ⁷ copies/mL	590	44,394	4	0,678	561	42,117	1	0,178	3,823	Algorithm converged.	0,426	34,305	0,5	Algorithm converged.	-0,249	1,248	3,803	Algorithm converged.	0,426	33,925	0,3747			0,263	Algorithm converged.	0,029	2,345
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Fibrin D dimer increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	4	1,111	0,484	Algorithm converged.	0,088	2,657	-0,571	Algorithm converged.	-1,886	0,745	0,486	Algorithm converged.	0,09	2,64	0,4453	0,0401		2,056	Algorithm converged.	0,379	11,153
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE *	Algorithm not converged.	NE	NE	-1,463	Algorithm converged.	-3,107	0,18	NE	Algorithm not converged.	NE	NE	0,2505			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	5	0,847	561	42,117	1	0,178	4,786	Algorithm converged.	0,557	41,096	0,669	Algorithm converged.	-0,149	1,487	4,754	Algorithm converged.	0,557	40,567	0,2184			0,21	Algorithm converged.	0,025	1,795
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Heart rate decreased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	Algorithm not converged.	NE	NE	0,4716			NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
		Hepatic enzyme increased	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	Algorithm not converged.	NE	NE	0,4994			NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	Algorithm not converged.	NE	NE	1			NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		International normalised ratio increased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339	Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Prothrombin time prolonged	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339	Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Serum ferritin increased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Transaminases increased	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Weight decreased	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27,84	4	1,081	360	27,027	1	0,278	3,923		Algorithm converged.	0,436	35,273	0,803		Algorithm converged.	-0,382	1,989	3,892		Algorithm converged.	0,437	34,653	0,3735	0,0635	0,257		Algorithm converged.	0,029	2,288	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	3	1,639	0,385		Algorithm converged.	0,04	3,735	-1,002		Algorithm converged.	-3,224	1,219	0,389		Algorithm converged.	0,041	3,698	0,6272		2,574		Algorithm converged.	0,27	24,495	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	4	1,951	NE	*	Algorithm not converged.	NE	NE	-1,951		Algorithm converged.	-3,845	-0,058	NE	*	Algorithm not converged.	NE	NE	0,1255		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	4	0,678	561	42,117	5	0,891	0,759		Algorithm converged.	0,203	2,841	-0,213		Algorithm converged.	-1,235	0,808	0,761		Algorithm converged.	0,205	2,818	0,7474		1,315		Algorithm converged.	0,355	4,871	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dehydration	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Haemochromatosis	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperkalaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Hypokalaemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Hyponatraemia	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
		Malnutrition	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE	NE	NE	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	3	0,833	0,322		Algorithm converged.	0,033	3,115	-0,563		Algorithm converged.	-1,641	0,515	0,324		Algorithm converged.	0,034	3,103	0,3672	0,8318	3,083	Algorithm converged.	0,322	29,504
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm not converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37		Algorithm converged.	0,038	3,588	-0,917		Algorithm converged.	-2,877	1,043	0,373		Algorithm converged.	0,039	3,558	0,6255		2,678	Algorithm converged.	0,281	25,52
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	3	0,535	0,633		Algorithm converged.	0,105	3,8	-0,196		Algorithm converged.	-0,96	0,569	0,634		Algorithm converged.	0,106	3,779	0,6794		1,578	Algorithm converged.	0,265	9,406
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Arthralgia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	2	0,556	NE	*	Algorithm not converged.	NE	NE	-0,556		Algorithm converged.	-1,323	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthritis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Back pain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Costochondritis	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Intervertebral disc protrusion	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Joint effusion	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Musculoskeletal pain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Myalgia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain in extremity	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk																	
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	NE		NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
		Gastric cancer	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	NE		NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
		Squamous cell carcinoma of skin	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE	NE		NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE		NE		

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Nervous system disorders	--	<=10^5 copies/mL	370	27,84	3	0,811	360	27,027	1	0,278	2,935	Algorithm converged.	0,304	28,344	0,533	Algorithm converged.	-0,53	1,596	2,919	Algorithm converged.	0,305	27,931	0,6241	0,1218	0,343	Algorithm converged.	0,036	3,278
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE *	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE *	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	4	1,951	0,276	Algorithm converged.	0,031	2,493	-1,405	Algorithm converged.	-3,579	0,769	0,28	Algorithm converged.	0,032	2,483	0,3758		3,571	Algorithm converged.	0,403	31,658
			>10^7 copies/mL	590	44,394	7	1,186	561	42,117	4	0,713	1,672	Algorithm converged.	0,487	5,743	0,473	Algorithm converged.	-0,644	1,591	1,664	Algorithm converged.	0,49	5,653	0,5483		0,601	Algorithm converged.	0,177	2,042
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	3,448	Algorithm converged.	-3,193	10,09	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Ageusia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE *	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE *	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE *	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anosmia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE *	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE *	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE *	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bell's palsy	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dementia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dizziness	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27		Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	3,448		Algorithm not converged.	-3,193	10,09	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Facial paresis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	
		Headache	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	1	0,278	1,951		Algorithm converged.	0,176	21,612	0,263		Algorithm converged.	-0,661	1,187	1,946		Algorithm converged.	0,177	21,366	1		0,514	Algorithm converged.	0,047	5,642
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463		Algorithm not converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	1	3,448	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	3,448		Algorithm not converged.	-3,193	10,09	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hypogeusia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyposmia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Parosmia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Presyncope	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Syncope	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Tremor	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
		Ectopic pregnancy	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pregnancy	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	1	0,178	2,862		Algorithm converged.	0,297	27,596	0,33		Algorithm converged.	-0,342	1,002	2,853		Algorithm converged.	0,298	27,342	0,6248		0,351	Algorithm converged.	0,037	3,36
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Depression	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		1,052		Algorithm converged.	0,066	16,773		1,052		Algorithm converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Insomnia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Mental status changes	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Renal and urinary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052		Algorithm not converged.	0,066	16,773
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute kidney injury	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905		Algorithm converged.	0,172	21,065	0,161	Algorithm converged.	-0,424	0,745	1,902		Algorithm converged.	0,173	20,914	1		0,526	Algorithm converged.	0,048	5,783	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Heavy menstrual bleeding	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Suppressed lactation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Testicular pain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	370	27,84	8	2,162	360	27,027	7	1,944	1,114	Algorithm converged.	0,4	3,106	0,218	Algorithm converged.	-1,839	2,275	1,112	Algorithm converged.	0,407	3,035	0,8359	0,4333	0,899	Algorithm converged.	0,33	2,454		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	3	1,911	183	13,739	3	1,639	1,169	Algorithm converged.	0,233	5,875	0,271	Algorithm converged.	-2,552	3,095	1,166	Algorithm converged.	0,239	5,693	1		0,858	Algorithm converged.	0,176	4,19		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	2	1,093	205	15,39	7	3,415	0,313	Algorithm converged.	0,064	1,524	-2,322	Algorithm converged.	-5,228	0,585	0,32	Algorithm converged.	0,067	1,521	0,181		3,124	Algorithm converged.	0,657	14,85		
			>10 ⁷ copies/mL	590	44,394	14	2,373	561	42,117	24	4,278	0,544	Algorithm converged.	0,278	1,062	-1,905	Algorithm converged.	-3,982	0,171	0,555	Algorithm converged.	0,29	1,061	0,0707		1,803	Algorithm converged.	0,942	3,45		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE	*	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Asthma	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1		1,028	Algorithm converged.	0,065	16,369	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bronchial secretion retention	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
		Bronchospasm	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
		Chronic obstructive pulmonary disease	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE
		Cough	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	3	0,833	0,647		Algorithm converged.	0,107	3,893	-0,293		Algorithm converged.	-1,493	0,907	0,649		Algorithm converged.	0,109	3,859	0,6824	0,7398	1,542	Algorithm converged.	0,259	9,172	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	2	1,093	205	15,39	2	0,976	1,122	Algorithm converged.	0,156	8,044	0,117	Algorithm converged.	-1,902	2,137	1,12	Algorithm converged.	0,159	7,872	1		0,893	Algorithm converged.	0,127	6,273
			>10 ⁷ copies/mL	590	44,394	7	1,186	561	42,117	3	0,535	2,233	Algorithm converged.	0,575	8,679	0,652	Algorithm converged.	-0,41	1,714	2,219	Algorithm converged.	0,577	8,537	0,3432		0,451	Algorithm converged.	0,117	1,734
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	2	0,556	0,973	Algorithm converged.	0,136	6,944	-0,015	Algorithm converged.	-1,086	1,056	0,973	Algorithm converged.	0,138	6,87	1	0,5047	1,028	Algorithm converged.	0,146	7,257
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	1	0,546	1,167	Algorithm converged.	0,072	18,806	0,09	Algorithm converged.	-1,549	1,73	1,166	Algorithm converged.	0,074	18,483	1		0,858	Algorithm converged.	0,054	13,604
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE *	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	5	0,847	561	42,117	11	1,961	0,427	Algorithm converged.	0,148	1,238	-1,113	Algorithm converged.	-2,478	0,252	0,432	Algorithm converged.	0,151	1,236	0,1327		2,314	Algorithm converged.	0,809	6,617
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea exertional	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE *	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Epistaxis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	0,637	Algorithm converged.	-0,607	1,881	NE *	Algorithm not converged.	NE	NE	0,4618		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,0317	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE	*	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nasal congestion	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Oropharyngeal pain	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Productive cough	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pulmonary congestion	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pulmonary mass	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	*	Algorithm converged.	-0,607	1,881	NE	*	Algorithm not converged.	NE	NE	0,4618		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	*	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory distress	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	*	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory tract congestion	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	*	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sinus congestion	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE	*	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Skin and subcutaneous tissue disorders	--	<=10^5 copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541	Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,1563	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	2	1,093	NE	*	Algorithm not converged.	NE	NE	-1,093	Algorithm converged.	-2,599	0,413	NE	*	Algorithm not converged.	NE	NE	0,5015		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	1	0,488	1,121		Algorithm converged.	0,07	18,049	0,059	Algorithm converged.	-1,373	1,491	1,12		Algorithm converged.	0,071	17,781	1		0,893	Algorithm converged.	0,056	14,17	
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	3	0,535	0,951		Algorithm converged.	0,191	4,73	-0,026	Algorithm converged.	-0,859	0,807	0,951		Algorithm converged.	0,193	4,691	1		1,052	Algorithm converged.	0,213	5,189	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acne	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pruritus	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm not converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Rash	<=10 ⁵ copies/mL	370	27,84	2	0,541	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,541		Algorithm converged.	-0,207	1,288	NE	*	Algorithm not converged.	NE	NE	0,4994	0,2949		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	1	0,488	1,121		Algorithm converged.	0,07	18,049	0,059		Algorithm converged.	-1,373	1,491	1,12		Algorithm converged.	0,071	17,781	1		0,893	Algorithm converged.	0,056	14,17	
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	2	0,357	1,428		Algorithm converged.	0,238	8,581	0,152		Algorithm converged.	-0,605	0,909	1,426		Algorithm converged.	0,239	8,504	1		0,701	Algorithm converged.	0,118	4,18	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Surgical and medical procedures	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Hospitalisation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm not converged.	NE	NE	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Vascular disorders --		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	2	0,556	NE	*	Algorithm not converged.	NE	NE	-0,556	NE	*	Algorithm not converged.	NE	NE	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	NE	*	Algorithm not converged.	NE	NE	0,637	NE	*	Algorithm not converged.	NE	NE	0,4618	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	3	0,535	0,316	NE	*	Algorithm not converged.	0,033	3,045	-0,365	NE	*	Algorithm not converged.	0,033	3,045	0,317	NE	*	Algorithm not converged.	0,033	3,038	0,3622	3,155	NE	0,329	30,242
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Flushing		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	NE	*	Algorithm not converged.	NE	NE	0,169	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Hypertension		<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	2	0,556	NE	*	Algorithm not converged.	NE	NE	-0,556	NE	*	Algorithm not converged.	NE	NE	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429	NE	NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	0,637	NE	*	Algorithm not converged.	NE	NE	0,637	NE	*	Algorithm not converged.	NE	NE	0,4618	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		May-Thurner syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm not converged.	NE	NE	0,171	NE	Algorithm not converged.	NE	NE	0,4874	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Thrombophlebitis superficial	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm not converged.	NE	NE	0,171	NE	Algorithm not converged.	NE	NE	0,4874	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Country	Blood and lymphatic system disorders	--	USA	1237	93,08	6	0,49	1239	93,02	2	0,16	3,015	Algorithm converged.	0,607	14,97	0,324	Algorithm converged.	-0,12	0,771	3,005	Algorithm converged.	0,608	14,86	0,1787	1	0,333	Algorithm converged.	0,067	1,646				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Eosinophilia		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Iron deficiency anaemia		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	Algorithm not converged.	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Leukocytosis		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	Algorithm not converged.	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Leukopenia		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	Algorithm not converged.	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Lymphopenia		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	Algorithm not converged.	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		
	Thrombocytopenia		USA	1237	93,08	2	0,16	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,06	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495	NE	Algorithm not converged.	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Thrombocytosis	USA	1237	93,08	2	0,16	1239	93,02	1	0,08	2,005	Algorithm converged.	0,182	22,14	0,081	Algorithm converged.	-0,19	0,355	2,003	Algorithm converged.	0,182	22,06	0,6245	1	0,499	Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac disorders	--	USA	1237	93,08	4	0,32	1239	93,02	6	0,48	0,667	Algorithm converged.	0,188	2,368	-0,161	Algorithm converged.	-0,66	0,339	0,668	Algorithm converged.	0,189	2,36	0,7534	1	1,498	Algorithm converged.	0,424	5,294
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Angina pectoris	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arrhythmia neonatal	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Palpitations	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sinus tachycardia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tachycardia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Eye disorders	USA	1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE	*	Algorithm not converged.	NE	NE	-1,075		Algorithm converged.	-3,17	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Cataract	USA	1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE	*	Algorithm not converged.	NE	NE	-1,075		Algorithm converged.	-3,17	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Gastrointestinal disorders	USA	1237	93,08	8	0,65	1239	93,02	12	0,97	0,666		Algorithm converged.	0,271	1,634	-0,322		Algorithm converged.	-1,03	0,383	0,668		Algorithm converged.	0,274	1,628	0,3712	0,5642	1,498		Algorithm converged.	0,614	3,651
			MEX	92	6,922	1	1,09	93	6,982	3	3,23	0,33		Algorithm converged.	0,034	3,229	-2,139		Algorithm converged.	-6,31	2,031	0,337		Algorithm converged.	0,036	3,18	0,6209		2,968		Algorithm converged.	0,314	28,01
		Abdominal distension	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Abdominal pain	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Abdominal pain upper	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic gastritis	USA	1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	1	1,09	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	1,087	Algorithm converged.	-1,03	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
		Constipation	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Diarrhoea	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	2	2,15	NE	*	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,1	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
		Gastric ulcer	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastritis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Gastroesophageal reflux disease	USA	1237	93,08	2	0,16	1239	93,02	1	0,08	2,005	Algorithm converged.	0,182	22,14	0,081	Algorithm converged.	-0,19	0,355	2,003	Algorithm converged.	0,182	22,06	0,6245	0,1893	0,499	Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,17	1,021	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Nausea	USA	1237	93,08	4	0,32	1239	93,02	4	0,32	1,002	Algorithm converged.	0,25	4,014	0,001	Algorithm converged.	-0,45	0,448	1,002	Algorithm converged.	0,251	3,996	1	1	0,998	Algorithm converged.	0,25	3,983
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	USA	1237	93,08	0	0	1239	93,02	5	0,4	NE *	Algorithm not converged.	NE	NE	-0,404	Algorithm converged.	-0,76	-0,05	NE *	Algorithm not converged.	NE	NE	0,0622		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	1237	93,08	9	0,73	1239	93,02	16	1,29	0,56	Algorithm converged.	0,247	1,273	-0,564	Algorithm converged.	-1,35	0,223	0,563	Algorithm converged.	0,25	1,27	0,1607	0,114	1,775	Algorithm converged.	0,787	4,001
			MEX	92	6,922	0	0	93	6,982	3	3,23	NE *	Algorithm not converged.	NE	NE	-3,226	Algorithm converged.	-6,82	0,365	NE *	Algorithm not converged.	NE	NE	0,2459		NE	Algorithm not converged.	NE	NE
		Chest discomfort	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Fatigue	USA	MEX	1237	93,08	2	0,16	1239	93,02	3	0,24	0,667	Algorithm converged.	0,111	4	-0,08	Algorithm converged.	-0,43	0,273	0,668	Algorithm converged.	0,112	3,989	1	1	1,498	Algorithm converged.	0,251	8,947		
			92	6,922	0	0	93	6,982	0	0	NE	*	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
Fever neonatal	USA	MEX	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Multiple organ dysfunction syndrome	USA	MEX	1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	2	2,15	NE	*	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,1	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973	NE	Algorithm not converged.	NE	NE	
Non-cardiac chest pain	USA	MEX	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99		
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Oedema peripheral	USA	MEX	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	Algorithm not converged.	NE	NE	
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Pain	USA	MEX	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99		
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
Peripheral swelling	USA	MEX	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99		
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Pyrexia	USA	1237	93,08	2	0,16	1239	93,02	5	0,4	0,4	Algorithm converged.	0,077	2,064	-0,242	Algorithm converged.	-0,66	0,176	0,401	Algorithm converged.	0,078	2,061	0,4525	0,4316	2,496	Algorithm converged.	0,485	12,84
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,17	1,021	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Swelling face	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Immune system disorders	--	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Seasonal allergy	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	1237	93,08	22	1,78	1239	93,02	31	2,5	0,706	Algorithm converged.	0,406	1,226	-0,724	Algorithm converged.	-1,86	0,416	0,711	Algorithm converged.	0,414	1,221	0,2137	1	1,407	Algorithm converged.	0,819	2,416

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Bacteraemia		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Breast abscess		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Bronchitis		USA	1237	93,08	4	0,32	1239	93,02	1	0,08	4,016		Algorithm converged.	0,448	35,98	0,243		Algorithm converged.	-0,11	0,596	4,006		Algorithm converged.	0,448	35,8	0,218	1	0,25		Algorithm converged.	0,028	2,23
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Cellulitis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Clostridium difficile colitis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastroenteritis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Kidney infection		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Lung abscess	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pharyngitis streptococcal	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	USA	1237	93,08	7	0,57	1239	93,02	14	1,13	0,498		Algorithm converged.	0,2	1,238	-0,564	Algorithm converged.	-1,29	0,158	0,501		Algorithm converged.	0,203	1,237	0,126	1	1,997	Algorithm converged.	0,809	4,93	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rectal abscess	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Sepsis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Sinusitis	USA	1237	93,08	4	0,32	1239	93,02	3	0,24	1,337		Algorithm converged.	0,299	5,984	0,081	Algorithm converged.	-0,34	0,5	1,335		Algorithm converged.	0,3	5,955	0,726	1	0,749	Algorithm converged.	0,168	3,339
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Superinfection bacterial	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Tooth abscess	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Upper respiratory tract infection	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Urinary tract infection	USA	1237	93,08	4	0,32	1239	93,02	1	0,08	4,016		Algorithm converged.	0,448	35,98	0,243	Algorithm converged.	-0,11	0,596	4,006		Algorithm converged.	0,448	35,8	0,218	1	0,25	Algorithm converged.	0,028	2,23
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Injury, poisoning and procedural complications	--	USA	1237	93,08	7	0,57	1239	93,02	1	0,08	7,046		Algorithm converged.	0,866	57,35	0,485	Algorithm converged.	0,038	0,932	7,011		Algorithm converged.	0,864	56,9	0,0386	1	0,143	Algorithm converged.	0,018	1,158
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason		95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Ankle fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cervical vertebral fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Contusion	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fall	USA	1237	93,08	2	0,16	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,06	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infusion related reaction	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ligament sprain	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Skin laceration	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tibia fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	USA	1237	93,08	26	2,1	1239	93,02	23	1,86	1,135		Algorithm converged.	0,644	2	0,246	Algorithm converged.	-0,85	1,343	1,132		Algorithm converged.	0,65	1,973	0,661	1	0,883	Algorithm converged.	0,507	1,539	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Activated partial thromboplastin time prolonged	USA	1237	93,08	7	0,57	1239	93,02	7	0,57	1,002		Algorithm converged.	0,35	2,864	0,001	Algorithm converged.	-0,59	0,592	1,002		Algorithm converged.	0,352	2,847	0,9976	1	0,998	Algorithm converged.	0,351	2,838	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Alanine aminotransferase increased	USA	1237	93,08	4	0,32	1239	93,02	4	0,32	1,002		Algorithm converged.	0,25	4,014	0,001	Algorithm converged.	-0,45	0,448	1,002		Algorithm converged.	0,251	3,996	1	1	0,998	Algorithm converged.	0,25	3,983	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Aspartate aminotransferase increased	USA	1237	93,08	2	0,16	1239	93,02	1	0,08	2,005	Algorithm converged.	0,182	22,14	0,081	Algorithm converged.	-0,19	0,355	2,003	Algorithm converged.	0,182	22,06	0,6245	1	0,499	Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bleeding time prolonged	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood bicarbonate decreased	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood creatine phosphokinase increased	USA	1237	93,08	5	0,4	1239	93,02	2	0,16	2,51	Algorithm converged.	0,486	12,96	0,243	Algorithm converged.	-0,18	0,661	2,504	Algorithm converged.	0,487	12,88	0,2881	1	0,399	Algorithm converged.	0,078	2,054
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Blood lactate dehydrogenase increased	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		C-reactive protein increased	USA	1237	93,08	7	0,57	1239	93,02	7	0,57	1,002	Algorithm converged.	0,35	2,864	0,001	Algorithm converged.	-0,59	0,592	1,002	Algorithm converged.	0,352	2,847	0,9976	1	0,998	Algorithm converged.	0,351	2,838
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fibrin D dimer increased	USA	1237	93,08	7	0,57	1239	93,02	9	0,73	0,778	Algorithm converged.	0,289	2,095	-0,161	Algorithm converged.	-0,79	0,471	0,779	Algorithm converged.	0,291	2,085	0,6183	1	1,284	Algorithm converged.	0,48	3,436

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Heart rate decreased	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hepatic enzyme increased	USA	1237	93,08	2	0,16	1239	93,02	2	0,16	1,002		Algorithm converged.	0,141	7,122	0		Algorithm converged.	-0,32	0,317	1,002		Algorithm converged.	0,141	7,099	1	1	0,998		Algorithm converged.	0,141	7,076
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		International normalised ratio increased	USA	1237	93,08	2	0,16	1239	93,02	1	0,08	2,005		Algorithm converged.	0,182	22,14	0,081		Algorithm converged.	-0,19	0,355	2,003		Algorithm converged.	0,182	22,06	0,6245	1	0,499		Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Prothrombin time prolonged	USA	1237	93,08	2	0,16	1239	93,02	1	0,08	2,005		Algorithm converged.	0,182	22,14	0,081		Algorithm converged.	-0,19	0,355	2,003		Algorithm converged.	0,182	22,06	0,6245	1	0,499		Algorithm converged.	0,045	5,498
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Serum ferritin increased	USA	1237	93,08	0	0	1239	93,02	3	0,24	NE	*	Algorithm not converged.	NE	NE	-0,242		Algorithm converged.	-0,52	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Transaminases increased	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	1237	93,08	9	0,73	1239	93,02	13	1,05	0,691		Algorithm converged.	0,294	1,623	-0,322		Algorithm converged.	-1,06	0,417	0,693		Algorithm converged.	0,297	1,616	0,3939	1	1,442		Algorithm converged.	0,619	3,361
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	1237	93,08	0	0	1239	93,02	6	0,48	NE	*	Algorithm not converged.	NE	NE	-0,484		Algorithm converged.	-0,87	-0,1	NE	*	Algorithm not converged.	NE	NE	0,0311		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Haemochromatosis	USA	1237	93,08	1	0,08	1239	93,02	3	0,24	0,333		Algorithm converged.	0,035	3,209	-0,161		Algorithm converged.	-0,48	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995		Algorithm converged.	0,312	28,76
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	USA	1237	93,08	3	0,24	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,243		Algorithm converged.	-0,03	0,517	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperkalaemia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	1237	93,08	2	0,16	1239	93,02	3	0,24	0,667		Algorithm converged.	0,111	4	-0,08		Algorithm converged.	-0,43	0,273	0,668		Algorithm converged.	0,112	3,989	1	1	1,498		Algorithm converged.	0,251	8,947
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Malnutrition	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal and connective tissue disorders	USA	1237	93,08	4	0,32	1239	93,02	10	0,81	0,399		Algorithm converged.	0,125	1,275	-0,484	Algorithm converged.	-1,07	0,106	0,401		Algorithm converged.	0,126	1,274	0,1783	1	2,496	Algorithm converged.	0,785	7,937	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthralgia	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arthritis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Back pain	USA	1237	93,08	0	0	1239	93,02	3	0,24	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,52	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Costochondritis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Intervertebral disc protrusion	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Joint effusion	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal pain	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Myalgia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pain in extremity	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Gastric cancer	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Squamous cell carcinoma of skin	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	USA	1237	93,08	12	0,97	1239	93,02	11	0,89	1,094		Algorithm converged.	0,481	2,488	0,082	Algorithm converged.	-0,67	0,838	1,093		Algorithm converged.	0,484	2,467	0,8311	1	0,915	Algorithm converged.	0,405	2,066	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ageusia	USA	1237	93,08	1	0,08	1239	93,02	3	0,24	0,333		Algorithm converged.	0,035	3,209	-0,161	Algorithm converged.	-0,48	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995	Algorithm converged.	0,312	28,76	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anosmia	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bell's palsy	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dementia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Dizziness	USA	1237	93,08	2	0,16	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,06	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Facial paresis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Headache	USA	1237	93,08	3	0,24	1239	93,02	4	0,32	0,751		Algorithm converged.	0,168	3,361	-0,08	Algorithm converged.	-0,5	0,338	0,751		Algorithm converged.	0,168	3,349	1	1	1,331	Algorithm converged.	0,299	5,935	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypogeusia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyposmia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Parosmia	USA	1237	93,08	2	0,16	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,06	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Presyncope	USA	1237	93,08	0	0	1239	93,02	3	0,24	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,52	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Syncope	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	

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POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason		95% Lower CL	95% upper CL	p-value	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tremor	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ectopic pregnancy	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pregnancy	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Psychiatric disorders	USA	1237	93,08	3	0,24	1239	93,02	3	0,24	1,002		Algorithm converged.	0,202	4,972	0		Algorithm converged.	-0,39	0,388	1,002		Algorithm converged.	0,203	4,953	1	0,2626	0,998		Algorithm converged.	0,202	4,937
			MEX	92	6,922	1	1,09	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	1,087		Algorithm converged.	-1,03	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Anxiety	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	1	1,09	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	1,087	Algorithm converged.	-1,03	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
		Insomnia	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Mental status changes	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,08	1	0,08	1239	93,02	3	0,24	0,333		Algorithm converged.	0,035	3,209	-0,161	Algorithm converged.	-0,48	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	1	2,995	Algorithm converged.	0,312	28,76	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Reproductive system and breast disorders	--	USA	1237	93,08	2	0,16	1239	93,02	1	0,08	2,005		Algorithm converged.	0,182	22,14	0,081	Algorithm converged.	-0,19	0,355	2,003		Algorithm converged.	0,182	22,06	0,6245	1	0,499	Algorithm converged.	0,045	5,498	

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Heavy menstrual bleeding	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Suppressed lactation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Testicular pain	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,08	26	2,1	1239	93,02	40	3,23	0,644		Algorithm converged.	0,39	1,061	-1,127		Algorithm converged.	-2,39	0,141	0,651		Algorithm converged.	0,4	1,06	0,0819	0,7589	1,536		Algorithm converged.	0,943	2,501
			MEX	92	6,922	1	1,09	93	6,982	1	1,08	1,011		Algorithm converged.	0,062	16,41	0,012		Algorithm converged.	-2,97	2,992	1,011		Algorithm converged.	0,064	15,92	1		0,989		Algorithm converged.	0,063	15,58
		Acute respiratory distress syndrome	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	USA	1237	93,08	0	0	1239	93,02	4	0,32	NE	*	Algorithm not converged.	NE	NE	-0,323		Algorithm converged.	-0,64	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1247		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Asthma	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Bronchial secretion retention	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Bronchospasm	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Chronic obstructive pulmonary disease	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Cough	USA	1237	93,08	11	0,89	1239	93,02	8	0,65	1,381	Algorithm converged.	0,553	3,444	0,244	Algorithm converged.	-0,44	0,931	1,377	Algorithm converged.	0,556	3,412	0,4875	1	0,726	Algorithm converged.	0,293	1,799	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Dyspnoea	USA	1237	93,08	7	0,57	1239	93,02	16	1,29	0,435	Algorithm converged.	0,178	1,061	-0,725	Algorithm converged.	-1,48	0,029	0,438	Algorithm converged.	0,181	1,061	0,06	0,1287	2,282	Algorithm converged.	0,942	5,528	
			MEX	92	6,922	1	1,09	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	1,087	Algorithm converged.	-1,03	3,206	NE	*	Algorithm not converged.	NE	NE	0,4973	NE	NE	Algorithm not converged.	NE	NE
		Dyspnoea exertional	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Epistaxis	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	1237	93,08	2	0,16	1239	93,02	6	0,48	0,333	Algorithm converged.	0,067	1,652	-0,323	Algorithm converged.	-0,77	0,124	0,334	Algorithm converged.	0,068	1,651	0,2883	1	2,995	Algorithm converged.	0,606	14,81	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Nasal congestion	USA	1237	93,08	1	0,08	1239	93,02	2	0,16	0,5	Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,36	0,193	0,501	Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,99	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Oropharyngeal pain	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	USA	1237	93,08	0	0	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,17	1,021	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
		Productive cough	USA	1237	93,08	2	0,16	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,162	Algorithm converged.	-0,06	0,386	NE	*	Algorithm not converged.	NE	NE	0,2495	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pulmonary congestion	USA	1237	93,08	3	0,24	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,243	Algorithm converged.	-0,03	0,517	NE	*	Algorithm not converged.	NE	NE	0,1245	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pulmonary mass	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory tract congestion	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sinus congestion	USA	1237	93,08	0	0	1239	93,02	4	0,32	NE *	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,64	-0,01	NE	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Skin and subcutaneous tissue disorders	--	USA	1237	93,08	6	0,49	1239	93,02	6	0,48	1,002	Algorithm converged.	0,322	3,114	0,001	Algorithm converged.	-0,55	0,548	1,002	Algorithm converged.	0,324	3,097	0,9978	1	0,998	Algorithm converged.	0,323	3,087
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acne	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pruritus	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Rash	USA	1237	93,08	6	0,49	1239	93,02	4	0,32	1,505	Algorithm converged.	0,424	5,346	0,162	Algorithm converged.	-0,34	0,662	1,502	Algorithm converged.	0,425	5,311	0,5477	1	0,666	Algorithm converged.	0,188	2,353
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	USA	1237	93,08	2	0,16	1239	93,02	5	0,4	0,4	Algorithm converged.	0,077	2,064	-0,242	Algorithm converged.	-0,66	0,176	0,401	Algorithm converged.	0,078	2,061	0,4525	1	2,496	Algorithm converged.	0,485	12,84
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Flushing	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypertension	USA	1237	93,08	1	0,08	1239	93,02	3	0,24	0,333	Algorithm converged.	0,035	3,209	-0,161	Algorithm converged.	-0,48	0,155	0,334	Algorithm converged.	0,035	3,205	0,6247	1	2,995	Algorithm converged.	0,312	28,76
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any AEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Thrombophlebitis superficial	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
All	Cardiac disorders	--	--	1329	100	2	0,15	1332	100	4	0,3	0,5		Algorithm converged.	0,091	2,737	-0,15	Algorithm converged.	-0,51	0,21	0,501			0,092	2,731	0,6871	1,995		Algorithm converged.	0,366	10,876
		Acute myocardial infarction	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994	NE		Algorithm not converged.	NE	NE
		Arrhythmia neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Cardiac failure congestive	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994	NE		Algorithm not converged.	NE	NE
		Coronary artery disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Tachycardia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	7	0,526	0,143		Algorithm converged.	0,018	1,16	-0,45	Algorithm converged.	-0,866	-0,035	0,143			0,018	1,162	0,0699	6,984		Algorithm converged.	0,86	56,688
		Death	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998	NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Pyrexia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998	NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	9	0,677	1332	100	28	2,102	0,318		Algorithm converged.	0,149	0,676	-1,425	Algorithm converged.	-2,313	-0,537	0,322		Algorithm converged.	0,153	0,68	0,0017		3,104	Algorithm converged.	1,47	6,553
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	--	1329	100	3	0,226	1332	100	8	0,601	0,374		Algorithm converged.	0,099	1,414	-0,375	Algorithm converged.	-0,862	0,112	0,376		Algorithm converged.	0,1	1,414	0,2256		2,661	Algorithm converged.	0,707	10,007
		COVID-19 pneumonia	--	1329	100	2	0,15	1332	100	7	0,526	0,285		Algorithm converged.	0,059	1,376	-0,375	Algorithm converged.	-0,816	0,066	0,286		Algorithm converged.	0,06	1,376	0,1789		3,492	Algorithm converged.	0,727	16,779
		Cellulitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	--	1329	100	5	0,376	1332	100	9	0,676	0,555		Algorithm converged.	0,186	1,661	-0,299	Algorithm converged.	-0,849	0,25	0,557		Algorithm converged.	0,187	1,657	0,4227		1,796	Algorithm converged.	0,603	5,345
		Pneumonia viral	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Investigations	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182	4,989		Algorithm converged.	0,584	42,643
		Dehydration	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	1	0,075	1332	100	14	1,051	0,071		Algorithm converged.	0,009	0,54	-0,976	Algorithm converged.	-1,543	-0,409	0,072		Algorithm converged.	0,009	0,544	0,0009		13,968	Algorithm converged.	1,839	106,074
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Hypoxia	--	1329	100	1	0,075	1332	100	5	0,375	0,2	Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures		--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders		--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Sex	Cardiac disorders	--	Male	641	48,23	2	0,31	634	47,6	1	0,16	1,981	Algorithm converged.	0,179	21,9	0,154	Algorithm converged.	-0,38	0,685	1,978	Algorithm converged.	0,18	21,76	1	0,052	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,77	0	0	698	52,4	3	0,43	NE *	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,92	0,056	NE *	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	*	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315	*	Algorithm converged.	-0,75	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	0,4256	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	5	0,72	0,202		Algorithm converged.	0,024	1,731	-0,571		Algorithm converged.	-1,26	0,116	0,203		Algorithm converged.	0,024	1,732	0,2178		4,928		Algorithm converged.	0,577	42,08
		Death	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	*	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Fever neonatal	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	*	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	2	0,29	NE	*	Algorithm not converged.	NE	NE	-0,287	*	Algorithm converged.	-0,68	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	1	0,14	1,015		Algorithm converged.	0,063	16,25	0,002		Algorithm converged.	-0,4	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986		Algorithm converged.	0,062	15,73

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pyrexia	Male	641	48,23	0	0	634	47,6	2	0,32	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm not converged.	-0,75	0,121	NE *	Algorithm not converged.	NE	NE	0,2471	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm not converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm not converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	641	48,23	8	1,25	634	47,6	15	2,37	0,522	Algorithm converged.	0,22	1,239	-1,118	Algorithm converged.	-2,58	0,344	0,528	Algorithm converged.	0,225	1,235	0,1339	0,0444	1,896	Algorithm converged.	0,809	4,44
			Female	688	51,77	1	0,15	698	52,4	13	1,86	0,077	Algorithm converged.	0,01	0,588	-1,717	Algorithm converged.	-2,76	-0,68	0,078	Algorithm converged.	0,01	0,595	0,0018	NE	12,814	Algorithm converged.	1,681	97,68
		Bacteraemia	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		COVID-19	Male	641	48,23	3	0,47	634	47,6	4	0,63	0,741	Algorithm converged.	0,165	3,322	-0,163	Algorithm converged.	-0,98	0,649	0,742	Algorithm converged.	0,167	3,301	0,7244	0,07	1,348	Algorithm converged.	0,303	5,999
			Female	688	51,77	0	0	698	52,4	4	0,57	NE *	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,13	-0,01	NE *	Algorithm not converged.	NE	NE	0,1245	NE	NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	Male	641	48,23	2	0,31	634	47,6	4	0,63	0,493	Algorithm converged.	0,09	2,701	-0,319	Algorithm converged.	-1,07	0,434	0,495	Algorithm converged.	0,091	2,69	0,4497	0,172	2,022	Algorithm converged.	0,372	11

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Female	688	51,77	0	0	698	52,4	3	0,43	NE *	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,92	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
		Cellulitis	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	Male	641	48,23	4	0,62	634	47,6	5	0,79	0,79	Algorithm converged.	0,211	2,955	-0,165	Algorithm converged.	-1,08	0,755	0,791		Algorithm converged.	0,213	2,933	0,7518	0,3583	1,264	Algorithm converged.	0,341	4,685
			Female	688	51,77	1	0,15	698	52,4	4	0,57	0,253	Algorithm converged.	0,028	2,265	-0,428	Algorithm converged.	-1,06	0,2	0,254		Algorithm converged.	0,028	2,263	0,3742		3,943	Algorithm converged.	0,442	35,19
		Pneumonia bacterial	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Pneumonia viral	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE		
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Sepsis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
		Injury, poisoning and procedural complications	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	3	0,44	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,436	Algorithm converged.	-0,06	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE		Algorithm not converged.	NE	NE		
		Ankle fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE		
		Cervical vertebral fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE		
		Fall	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE		
		Spinal compression fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Tibia fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
	Investigations	--	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	Male	641	48,23	1	0,16	634	47,6	1	0,16	0,989		Algorithm converged.	0,062	15,85	-0,002		Algorithm converged.	-0,44	0,433	0,989		Algorithm converged.	0,062	15,78	1	0,1067	1,011		Algorithm converged.	0,063	16,13
			Female	688	51,77	0	0	698	52,4	4	0,57	NE	*	Algorithm not converged.	NE	NE	-0,573		Algorithm converged.	-1,13	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
		Dehydration	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hypokalaemia	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	Male	641	48,23	1	0,16	634	47,6	1	0,16	0,989		Algorithm converged.	0,062	15,85	-0,002		Algorithm converged.	-0,44	0,433	0,989		Algorithm converged.	0,062	15,78	1	1	1,011		Algorithm converged.	0,063	16,13
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm not converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	3	0,44	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,436		Algorithm not converged.	-0,06	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE		Algorithm not converged.	NE	NE
		Facial paresis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm not converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Headache	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm not converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Syncope	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm not converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	1	0,14	1,015		Algorithm converged.	0,063	16,25	0,002		Algorithm converged.	-0,4	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986		Algorithm converged.	0,062	15,73
		Anxiety	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm not converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Depression	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Renal and urinary disorders	--	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315		Algorithm converged.	-0,75	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	0,0496	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Acute kidney injury		Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Nephrolithiasis		Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Renal failure		Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Respiratory, thoracic and mediastinal disorders	--	Male	641	48,23	1	0,16	634	47,6	10	1,58	0,098		Algorithm converged.	0,012	0,764	-1,421		Algorithm converged.	-2,44	-0,4	0,099		Algorithm converged.	0,013	0,77	0,0059	0,4263	10,11		Algorithm converged.	1,298	78,75
			Female	688	51,77	0	0	698	52,4	4	0,57	NE	*	Algorithm not converged.	NE	NE	-0,573		Algorithm converged.	-1,13	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE	
		Acute respiratory distress syndrome		Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315		Algorithm converged.	-0,75	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Dyspnoea	Male	641	48,23	0	0	634	47,6	3	0,47	NE	*	Algorithm not converged.	NE	NE	-0,473		Algorithm converged.	-1,01	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hypoxia	Male	641	48,23	1	0,16	634	47,6	5	0,79	0,197		Algorithm converged.	0,023	1,687	-0,633		Algorithm converged.	-1,39	0,121	0,198		Algorithm converged.	0,023	1,688	0,1222	1	5,055		Algorithm converged.	0,592	43,15
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Pulmonary mass	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
	Surgical and medical procedures	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hospitalisation	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		May-Thurner syndrome	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Age	Cardiac disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1	0,6628	1,975	Algorithm converged.	0,179	21,75
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	1	2,857	0,68	Algorithm converged.	0,041	11,25	-0,896	Algorithm converged.	-7,6	5,808	0,686	Algorithm converged.	0,044	10,61	1		1,457	Algorithm converged.	0,094	22,53
		Acute myocardial infarction	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Arrhythmia neonatal	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Tachycardia	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	1168	87,89	1	0,09	1183	88,81	4	0,338	0,253		Algorithm converged.	0,028	2,263	-0,253		Algorithm converged.	-0,623	0,118	0,253		Algorithm converged.	0,028	2,262	0,3745		3,949		Algorithm converged.	0,442	35,28
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571		Algorithm converged.	-17,85	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE		Algorithm not converged.	NE	NE
		Death	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Fever neonatal	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714		Algorithm converged.	-13,4	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013		Algorithm converged.	0,063	16,21	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1		0,987		Algorithm converged.	0,062	15,77
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pyrexia	18-64	1168	87,89	0	0	1183	88,81	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169		Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013		Algorithm converged.	0,063	16,21	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1		0,987		Algorithm converged.	0,062	15,77

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	NE	NE	1			NE			NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirinaemia	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	NE	NE	0,4968			NE			NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	18-64	1168	87,89	5	0,43	1183	88,81	18	1,522	0,278		Algorithm converged.	0,103	0,752	-1,093		Algorithm converged.	-1,885	-0,3	0,281		0,9662	3,554			2,914		Algorithm converged.	1,324	9,542	
			65-74	110	8,277	2	1,82	114	8,559	6	5,263	0,333		Algorithm converged.	0,066	1,688	-3,445		Algorithm converged.	-8,245	1,355	0,345		0,2808	2,895			2,914		Algorithm converged.	0,597	14,04	
			>=75	51	3,837	2	3,92	35	2,628	4	11,43	0,316		Algorithm converged.	0,055	1,831	-7,507		Algorithm converged.	-19,32	4,303	0,343		0,219	2,914			2,914		Algorithm converged.	0,564	15,05	
		Bacteraemia	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19	18-64	1168	87,89	2	0,17	1183	88,81	5	0,423	0,404		Algorithm converged.	0,078	2,087	-0,251		Algorithm converged.	-0,691	0,188	0,405		0,6208	2,468			1,93		Algorithm converged.	0,48	12,7	
			65-74	110	8,277	1	0,91	114	8,559	2	1,754	0,514		Algorithm converged.	0,046	5,748	-0,845		Algorithm converged.	-3,838	2,147	0,518		1	1,93			1,93		Algorithm converged.	0,178	20,98	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	18-64	1168	87,89	0	0	1183	88,81	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	2	1,82	114	8,559	2	1,754	1,037		Algorithm converged.	0,144	7,494	0,064	Algorithm converged.	-3,406	3,534	1,036		Algorithm converged.	0,149	7,229	1		0,965	Algorithm converged.	0,138	6,731
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,85	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE
		Cellulitis	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lung abscess	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Osteomyelitis acute	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	18-64	1168	87,89	3	0,26	1183	88,81	7	0,592	0,433		Algorithm converged.	0,112	1,677	-0,335	Algorithm converged.	-0,86	0,19	0,434		Algorithm converged.	0,113	1,675	0,3428		2,304	Algorithm converged.	0,597	8,887	
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	2	3,92	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	3,922	Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE	Algorithm not converged.	NE	NE	
		Pneumonia bacterial	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Injury, poisoning and procedural complications	--	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Ankle fracture	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

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ENDPOINT: AEs Grade >= 3

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Tibia fracture	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Weight decreased	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Metabolism and nutrition disorders	--	18-64	1168	87,89	0	0	1183	88,81	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,91	114	8,559	3	2,632	0,339		Algorithm converged.	0,035	3,314	-1,722	Algorithm converged.	-5,155	1,71	0,345		Algorithm converged.	0,036	3,271	0,6219		2,895	Algorithm converged.	0,306	27,41	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	*	Algorithm not converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm not converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	*	Algorithm not converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm not converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013		Algorithm converged.	0,063	16,21	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1		0,987		Algorithm converged.	0,062	15,77

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Nervous system disorders	--	18-64	1168	87,89	3	0,26	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,257	Algorithm converged.	-0,033	0,547	NE	*	Algorithm not converged.	NE	NE	0,1225		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
		Facial paresis	65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
		Headache	65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
		Syncope	65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013		Algorithm converged.	0,063	16,21	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1		0,987	Algorithm converged.	0,062	15,77	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
		Anxiety	65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Acute kidney injury	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	9	0,761	0,112		Algorithm converged.	0,014	0,884	-0,675	Algorithm converged.	-1,198	-0,15	0,113		Algorithm converged.	0,014	0,887	0,0212	0,5809	8,886	Algorithm converged.	1,128	70,03
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	4	11,43	NE	*	Algorithm not converged.	NE	NE	-11,429	Algorithm converged.	-21,97	-0,89	NE	*	Algorithm not converged.	NE	NE	0,0247		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	1168	87,89	0	0	1183	88,81	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Dyspnoea	18-64	1168	87,89	0	0	1183	88,81	3	0,254	NE *	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE *	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	1168	87,89	1	0,09	1183	88,81	4	0,338	0,253	Algorithm converged.	0,028	2,263	-0,253	Algorithm converged.	-0,623	0,118	0,253	Algorithm converged.	0,028	2,262	0,3745		3,949	Algorithm converged.	0,442	35,28
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Hospitalisation	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		May-Thurner syndrome	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37			-0,917		Algorithm converged.	0,038	3,588	-0,917		Algorithm converged.	-2,877	1,043	0,373		2,678		Algorithm converged.	0,281	25,52			
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951			-0,009		Algorithm converged.	0,059	15,24	-0,009		Algorithm converged.	-0,49	0,473	0,951		1,052		Algorithm converged.	0,066	16,77			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Acute myocardial infarction	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Arrhythmia neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Atrial fibrillation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Cardiac failure congestive	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Coronary artery disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1	0,1122	NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm not converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	5	0,891	NE	*	Algorithm not converged.	NE	NE	-0,891	Algorithm not converged.	-1,669	-0,114	NE	*	Algorithm not converged.	NE	NE	0,0273		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Death	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fever neonatal	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm not converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	NE	*	Algorithm not converged.	NE	NE	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
		Non-cardiac chest pain	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	NE	*	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
		Pyrexia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	NE	*	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
	Hepatobiliary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,24	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,77
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Cholecystitis acute	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Hyperbilirubinaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Infections and infestations	<=10^5 copies/mL	370	27,84	0	0	360	27,027	3	0,833	NE *	Algorithm not converged.	NE	NE	-0,833	Algorithm converged.	-1,772	0,106	NE *	Algorithm not converged.	NE	NE	0,1194	0,0357	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	2	1,274	183	13,739	2	1,093	1,168	Algorithm converged.	0,163	8,387	0,181	Algorithm converged.	-2,131	2,493	1,166	Algorithm converged.	0,166	8,179	1		0,858	Algorithm converged.	0,122	6,02
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	9	4,39	NE *	Algorithm not converged.	NE	NE	-4,39	Algorithm converged.	-7,195	-1,586	NE *	Algorithm not converged.	NE	NE	0,004		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	7	1,186	561	42,117	14	2,496	0,469	Algorithm converged.	0,188	1,171	-1,309	Algorithm converged.	-2,868	0,25	0,475	Algorithm converged.	0,193	1,169	0,0973		2,103	Algorithm converged.	0,855	5,173

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bacteraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	0,3842	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	3	0,508	561	42,117	4	0,713	0,712		Algorithm converged.	0,159	3,194	-0,205		Algorithm converged.	-1,107	0,698	0,713		Algorithm converged.	0,16	3,172	0,7194		1,402		Algorithm converged.	0,315	6,237
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19 pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463		Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	4	0,713	0,474		Algorithm converged.	0,086	2,596	-0,374		Algorithm converged.	-1,214	0,465	0,475		Algorithm converged.	0,087	2,585	0,441		2,103		Algorithm converged.	0,387	11,44
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Cellulitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	NE	NE	1		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	NE	NE	0,266		Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	0,171		Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Lung abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade ≥ 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			>10 ⁵ copies/mL - \leq 10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		
			>10 ⁶ copies/mL - \leq 10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	0,4874	NE	NE			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			
		Osteomyelitis acute	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		
			>10 ⁵ copies/mL - \leq 10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		
			>10 ⁶ copies/mL - \leq 10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	NE	*	Algorithm not converged.	NE	NE	1	NE	1	NE	NE			
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			
		Pneumonia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,27		
			>10 ⁵ copies/mL - \leq 10 ⁶ copies/mL	157	11,813	2	1,274	183	13,739	1	0,546	2,348	NE	*	Algorithm converged.	0,211	26,15	0,727	NE	*	Algorithm converged.	-1,326	2,781	2,331	NE	0,429	0,5973	0,429		
			>10 ⁶ copies/mL - \leq 10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463	NE	*	Algorithm not converged.	NE	NE	0,2505	NE	0,2505	NE	NE			
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	5	0,891	0,568	NE	*	Algorithm converged.	0,135	2,389	-0,383	NE	*	Algorithm converged.	-1,349	0,584	0,571	NE	0,4964	1,753	0,421		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			
		Pneumonia bacterial	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		
			>10 ⁵ copies/mL - \leq 10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np \leq 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia viral	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm not converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ankle fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tibia fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Investigations	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	4	0,713	NE	*	Algorithm not converged.	NE	NE	-0,713		Algorithm converged.	-1,409	-0,017	NE	*	Algorithm not converged.	NE	NE	0,0561		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Dehydration	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Rhabdomyolysis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Gastric cancer	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Facial paresis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo											Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
		Syncope	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	NE	NE	0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
	Psychiatric disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm not converged.	0,059	15,24	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1	1,052	0,066	16,77			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
		Anxiety	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,24	-0,009	Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,77	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,61	-0,008		Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1	0,2093	1,028		Algorithm converged.	0,065	16,37
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463		Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	9	1,604	NE	*	Algorithm not converged.	NE	NE	-1,604		Algorithm converged.	-2,644	-0,565	NE	*	Algorithm not converged.	NE	NE	0,0015		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspnoea	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE	*	Algorithm not converged.	NE	NE	-0,535		Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pulmonary mass	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	NE	NE	1		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	0,4874		Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hospitalisation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	0,4874		Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		May-Thurner syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Country	Cardiac disorders	--	USA	1237	93,078	2	0,162	1239	93,018	4	0,323	0,5	Algorithm converged.	0,091	2,735	-0,161	Algorithm converged.	-0,548	0,226	0,501	Algorithm converged.	0,092	2,729	0,6871	1	1,997	Algorithm converged.	0,366	10,882	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Arrhythmia neonatal		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Atrial fibrillation		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Cardiac failure congestive		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Coronary artery disease		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Tachycardia		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Peptic ulcer perforation	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		General disorders and administration site conditions	USA	1237	93,078	1	0,081	1239	93,018	5	0,404	0,2		Algorithm converged.	0,023	1,712	-0,323	Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	0,4316	4,992	Algorithm converged.	0,584	42,666	
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE	*	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
		Death	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	USA	1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE	*	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
		Non-cardiac chest pain	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatobiliary disorders	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	

Test for interaction based on RRR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Cholecystitis acute	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	USA	1237	93,078	7	0,566	1239	93,018	23	1,856	0,301		Algorithm converged.	0,129	0,704	-1,29		Algorithm converged.	-2,15	-0,43	0,305		Algorithm converged.	0,131	0,708	0,0033	0,7641	3,28		Algorithm converged.	1,413	7,617
			MEX	92	6,922	2	2,174	93	6,982	5	5,376	0,391		Algorithm converged.	0,074	2,069	-3,202		Algorithm converged.	-8,67	2,265	0,404		Algorithm converged.	0,08	2,032	0,4441		2,473		Algorithm converged.	0,492	12,426
		Bacteraemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19	USA	1237	93,078	1	0,081	1239	93,018	4	0,323	0,25		Algorithm converged.	0,028	2,238	-0,242		Algorithm converged.	-0,595	0,111	0,25		Algorithm converged.	0,028	2,237	0,3745	0,611	3,994		Algorithm converged.	0,447	35,679
			MEX	92	6,922	2	2,174	93	6,982	4	4,301	0,494		Algorithm converged.	0,088	2,768	-2,127		Algorithm converged.	-7,215	2,96	0,505		Algorithm converged.	0,095	2,692	0,6823		1,978		Algorithm converged.	0,371	10,539
		COVID-19 pneumonia	USA	1237	93,078	2	0,162	1239	93,018	6	0,484	0,333		Algorithm converged.	0,067	1,652	-0,323		Algorithm converged.	-0,769	0,124	0,334		Algorithm converged.	0,068	1,651	0,2883	0,4648	2,995		Algorithm converged.	0,606	14,811
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075		Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Cellulitis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
		Gastroenteritis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			
		Lung abscess	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			
		Osteomyelitis acute	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			
		Pneumonia	USA	1237	93,078	5	0,404	1239	93,018	9	0,726	0,555		Algorithm converged.	0,185	1,66	-0,322		Algorithm converged.	-0,913	0,268	0,556		Algorithm converged.	0,187	1,656	0,4226	1	1,797		Algorithm converged.	0,604	5,347				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			
		Pneumonia bacterial	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			
		Pneumonia viral	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			
		Sepsis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE			

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Injury, poisoning and procedural complications	--	USA	1237	93.078	3	0.243	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.243	Algorithm not converged.	-0.032	0.517	NE	*	Algorithm not converged.	NE	NE	0.1245		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Ankle fracture		USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cervical vertebral fracture		USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Fall		USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Spinal compression fracture		USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tibia fracture		USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Upper limb fracture		USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6.922	0	0	93	6.982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	USA	1237	93.078	1	0.081	1239	93.018	0	0	NE	*	Algorithm not converged.	NE	NE	0.081	Algorithm not converged.	-0.078	0.239	NE	*	Algorithm not converged.	NE	NE	0.4996		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	1237	93,078	1	0,081	1239	93,018	5	0,404	0,2		Algorithm converged.	0,023	1,712	-0,323		Algorithm converged.	-0,71	0,064	0,2	*	Algorithm converged.	0,023	1,712	0,2182	1	4,992		Algorithm converged.	0,584	42,666
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Musculoskeletal and connective tissue disorders	--	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastric cancer	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	USA	1237	93,078	3	0,243	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,243	Algorithm converged.	-0,032	0,517	NE *	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Facial paresis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Headache	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm not converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Syncope	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm not converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm not converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm not converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm not converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm not converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Renal failure	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm not converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,078	1	0,081	1239	93,018	13	1,049	0,076		Algorithm converged.	0,01	0,584	-0,968	Algorithm converged.	-1,557	-0,379	0,077		Algorithm converged.	0,01	0,588	0,0018	0,7064	12,979	Algorithm converged.	1,7	99,063	
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Acute respiratory distress syndrome	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	USA	1237	93,078	0	0	1239	93,018	3	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,516	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	USA	1237	93,078	0	0	1239	93,018	4	0,323	NE	*	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,639	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	1237	93,078	1	0,081	1239	93,018	5	0,404	0,2		Algorithm converged.	0,023	1,712	-0,323	Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	1	4,992	Algorithm converged.	0,584	42,666	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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ENDPOINT: AEs Grade >= 3

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Pneumothorax spontaneous	USA	1237	93,078	0	0	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Surgical and medical procedures	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vascular disorders	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk			
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL
All	Cardiac disorders	--	--	1329	100	2	0,15	1332	100	4	0,3	0,5		Algorithm converged.	0,091	2,737	-0,15	Algorithm converged.	-0,51	0,21	0,501			1,995	Algorithm converged.	0,366	10,876
		Acute myocardial infarction	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*		NE	Algorithm not converged.	NE	NE
		Arrhythmia neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
		Tachycardia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	7	0,526	0,143		Algorithm converged.	0,018	1,16	-0,45	Algorithm converged.	-0,866	-0,035	0,143			6,984	Algorithm converged.	0,86	56,688
		Death	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
		Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002			0,998	Algorithm converged.	0,062	15,935
		Pyrexia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002			0,998	Algorithm converged.	0,062	15,935
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk		Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	5	0,376	1332	100	14	1,051	0,356		Algorithm converged.	0,128	0,99	-0,675	Algorithm converged.	-1,314	-0,036	0,358		Algorithm converged.	0,129	0,991	0,0626		2,794	Algorithm converged.	1,009	7,734
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cellulitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	5	0,376	1332	100	9	0,676	0,555		Algorithm converged.	0,186	1,661	-0,299	Algorithm converged.	-0,849	0,25	0,557		Algorithm converged.	0,187	1,657	0,4227		1,796	Algorithm converged.	0,603	5,345
		Pneumonia bacterial	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

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If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Investigations	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643
		Dehydration	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders		--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders		--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders		--	1329	100	1	0,075	1332	100	14	1,051	0,071		Algorithm converged.	0,009	0,54	-0,976	Algorithm converged.	-1,543	-0,409	0,072		Algorithm converged.	0,009	0,544	0,0009		13,968	Algorithm converged.	1,839	106,074
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Hypoxia	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Pulmonary mass	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
	Surgical and medical procedures	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
	Vascular disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Cardiac disorders	--	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739	
	Arrhythmia neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	4	0,3	0,25	Algorithm converged.	0,028	2,24	-0,225	Algorithm converged.	-0,554	0,104	0,251	Algorithm converged.	0,028	2,239	0,3745		3,991	Algorithm converged.	0,447	35,66	
	Fever neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935	
	Pyrexia	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Hyperbilirubinaemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	9	0,677	1332	100	23	1,727	0,388	Algorithm converged.	0,179	0,842	-1,05	Algorithm converged.	-1,876	-0,223	0,392	Algorithm converged.	0,182	0,844	0,013		2,55	Algorithm converged.	1,184	5,49	
	Bacteraemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	COVID-19	--	--	1329	100	3	0,226	1332	100	6	0,45	0,5	Algorithm converged.	0,125	2,003	-0,225	Algorithm converged.	-0,666	0,216	0,501	Algorithm converged.	0,126	2	0,5071		1,995	Algorithm converged.	0,5	7,962	
	COVID-19 pneumonia	--	--	1329	100	2	0,15	1332	100	5	0,375	0,4	Algorithm converged.	0,077	2,065	-0,225	Algorithm converged.	-0,614	0,164	0,401	Algorithm converged.	0,078	2,063	0,4525		2,494	Algorithm converged.	0,485	12,834	
	Cellulitis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Clostridium difficile colitis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
All	Cardiac disorders	--	--	1329	100	2	0,15	1332	100	4	0,3	0,5		Algorithm converged.	0,091	2,737	-0,15	Algorithm converged.	-0,51	0,21	0,501			Algorithm converged.	0,092	2,731	0,6871	1,995		Algorithm converged.	0,366	10,876
		Acute myocardial infarction	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*		Algorithm not converged.	NE	NE	0,4994	NE		Algorithm not converged.	NE	NE
		Arrhythmia neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Cardiac failure congestive	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*		Algorithm not converged.	NE	NE	0,4994	NE		Algorithm not converged.	NE	NE
		Coronary artery disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Tachycardia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	7	0,526	0,143		Algorithm converged.	0,018	1,16	-0,45	Algorithm converged.	-0,866	-0,035	0,143			Algorithm converged.	0,018	1,162	0,0699	6,984		Algorithm converged.	0,86	56,688
		Death	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*		Algorithm not converged.	NE	NE	0,4998	NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002			Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Pyrexia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*		Algorithm not converged.	NE	NE	0,4998	NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002			Algorithm converged.	0,063	16,007	1	0,998		Algorithm converged.	0,062	15,935
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*		Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	1329	100	5	0,376	1332	100	14	1,051	0,356		Algorithm converged.	0,128	0,99	-0,675	Algorithm converged.	-1,314	-0,036	0,358		Algorithm converged.	0,129	0,991	0,0626		2,794	Algorithm converged.	1,009	7,734	
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cellulitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	5	0,376	1332	100	9	0,676	0,555		Algorithm converged.	0,186	1,661	-0,299	Algorithm converged.	-0,849	0,25	0,557		Algorithm converged.	0,187	1,657	0,4227		1,796	Algorithm converged.	0,603	5,345
		Pneumonia bacterial	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE	
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Investigations	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643
		Dehydration	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders		--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders		--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders		--	1329	100	1	0,075	1332	100	14	1,051	0,071		Algorithm converged.	0,009	0,54	-0,976	Algorithm converged.	-1,543	-0,409	0,072		Algorithm converged.	0,009	0,544	0,0009		13,968	Algorithm converged.	1,839	106,074
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Hypoxia	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Sex	Cardiac disorders	--	Male	641	48,23	2	0,31	634	47,6	1	0,16	1,981	Algorithm converged.	0,179	21,9	0,154	Algorithm converged.	-0,38	0,685	1,978	Algorithm converged.	0,18	21,76	1	0,052	0,506	Algorithm converged.	0,046	5,561
			Female	688	51,77	0	0	698	52,4	3	0,43	NE *	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,92	0,056	NE *	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*			NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315		Algorithm converged.	-0,75	0,121	NE	*			NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	5	0,72	0,202		Algorithm converged.	0,024	1,731	-0,571		Algorithm converged.	-1,26	0,116	0,203			4,928	Algorithm converged.	0,577	42,08	
		Death	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*			NE	Algorithm not converged.	NE	NE
		Fever neonatal	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*			NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	2	0,29	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,68	0,11	NE	*			NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*			NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	1	0,14	1,015		Algorithm converged.	0,063	16,25	0,002		Algorithm converged.	-0,4	0,402	1,015				0,986	Algorithm converged.	0,062	15,73

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pyrexia	Male	641	48,23	0	0	634	47,6	2	0,32	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,75	0,121	NE *	Algorithm not converged.	NE	NE	0,2471	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
	Hepatobiliary disorders	--	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	NE	NE	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	
		Cholecystitis acute	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	
		Hyperbilirubinaemia	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE		
	Infections and infestations	--	Male	641	48,23	4	0,62	634	47,6	7	1,1	0,562	Algorithm converged.	0,164	1,931	-0,48	Algorithm converged.	-1,5	0,536	0,565	Algorithm converged.	0,166	1,921	0,3832	0,2362	1,769	Algorithm converged.	0,521	6,014		
			Female	688	51,77	1	0,15	698	52,4	7	1	0,144	Algorithm converged.	0,018	1,171	-0,858	Algorithm converged.	-1,65	-0,07	0,145	Algorithm converged.	0,018	1,175	0,0696	6,9	Algorithm converged.	0,851	55,93			
		Bacteraemia	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE		
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE			
		Cellulitis	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973	NE	NE	NE	NE	NE		
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE			
		Clostridium difficile colitis	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE			

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm not converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Gastroenteritis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Lung abscess	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	Male	641	48,23	4	0,62	634	47,6	5	0,79	0,79		Algorithm converged.	0,211	2,955	-0,165	Algorithm converged.	-1,08	0,755	0,791		Algorithm converged.	0,213	2,933	0,7518	0,3583	1,264	Algorithm converged.	0,341	4,685	
			Female	688	51,77	1	0,15	698	52,4	4	0,57	0,253		Algorithm converged.	0,028	2,265	-0,428	Algorithm converged.	-1,06	0,2	0,254		Algorithm converged.	0,028	2,263	0,3742		3,943	Algorithm converged.	0,442	35,19	
		Pneumonia bacterial	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Pneumonia viral	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
	Injury, poisoning and procedural complications	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	3	0,44	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,436		Algorithm converged.	-0,06	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE		Algorithm not converged.	NE	NE
		Ankle fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Cervical vertebral fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Fall	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Tibia fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Investigations	--		Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Weight decreased			Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Metabolism and nutrition disorders	--		Male	641	48,23	1	0,16	634	47,6	1	0,16	0,989		Algorithm converged.	0,062	15,85	-0,002	Algorithm converged.	-0,44	0,433	0,989		Algorithm converged.	0,062	15,78	1	0,1067	1,011	Algorithm converged.	0,063	16,13	
			Female	688	51,77	0	0	698	52,4	4	0,57	NE	*	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,13	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE	
Dehydration			Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
Hyperglycaemia			Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Hypokalaemia			Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
Hyponatraemia			Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Type 2 diabetes mellitus	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	Male	641	48,23	1	0,16	634	47,6	1	0,16	0,989		Algorithm converged.	0,062	15,85	-0,002		Algorithm converged.	-0,44	0,433	0,989		Algorithm converged.	0,062	15,78	1	1	1,011		Algorithm converged.	0,063	16,13
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nervous system disorders	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,77	3	0,44	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,436	Algorithm converged.	-0,06	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE	Algorithm not converged.	NE	NE	
		Facial paresis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Headache	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Syncope	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Psychiatric disorders	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	1	0,14	1,015		Algorithm converged.	0,063	16,25	0,002	Algorithm converged.	-0,4	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986	Algorithm converged.	0,062	15,73	
		Anxiety	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Depression	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Renal and urinary disorders	--	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,75	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	0,0496	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Acute kidney injury	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Renal failure	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	641	48,23	1	0,16	634	47,6	10	1,58	0,098		Algorithm converged.	0,012	0,764	-1,421	Algorithm converged.	-2,44	-0,4	0,099		Algorithm converged.	0,013	0,77	0,0059	0,4263	10,11		Algorithm converged.	1,298	78,75	
			Female	688	51,77	0	0	698	52,4	4	0,57	NE	*	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,13	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE	
		Acute respiratory distress syndrome	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,75	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Chronic obstructive pulmonary disease	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Dyspnoea	Male	641	48,23	0	0	634	47,6	3	0,47	NE	*	Algorithm not converged.	NE	NE	-0,473		Algorithm converged.	-1,01	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hypoxia	Male	641	48,23	1	0,16	634	47,6	5	0,79	0,197		Algorithm converged.	0,023	1,687	-0,633		Algorithm converged.	-1,39	0,121	0,198		Algorithm converged.	0,023	1,688	0,1222	1	5,055		Algorithm converged.	0,592	43,15
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Pulmonary mass	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Surgical and medical procedures	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Hospitalisation	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
	Vascular disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		May-Thurner syndrome	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Age	Cardiac disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	2	0,169	0,506	Algorithm converged.	0,046	5,588	-0,083	Algorithm converged.	-0,371	0,205	0,506	Algorithm converged.	0,046	5,577	1	0,6628	1,975	Algorithm converged.	0,179	21,747	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68	Algorithm converged.	0,041	11,248	-0,896	Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1		1,457	Algorithm converged.	0,094	22,527
	Acute myocardial infarction		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Tachycardia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	1168	87,886	1	0,086	1183	88,814	4	0,338	0,253		Algorithm converged.	0,028	2,263	-0,253		Algorithm converged.	-0,623	0,118	0,253		Algorithm converged.	0,028	2,262	0,3745		3,949		Algorithm converged.	0,442	35,281
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571		Algorithm converged.	-17,846	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE		Algorithm not converged.	NE	NE
		Death	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm not converged.	NE	NE	2,662		Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Fever neonatal	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm not converged.	NE	NE	0,081		Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714		Algorithm not converged.	NE	NE	1,976		Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm not converged.	0,063	16,212	0,001		Algorithm not converged.	-0,235	0,237	1,013		Algorithm not converged.	0,063	16,174	1		0,987		Algorithm not converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pyrexia	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169		Algorithm not converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm not converged.	0,063	16,212	0,001		Algorithm not converged.	-0,235	0,237	1,013		Algorithm not converged.	0,063	16,174	1		0,987		Algorithm not converged.	0,062	15,766

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	18-64	1168	87,886	3	0,257	1183	88,814	11	0,93	0,274		Algorithm converged.	0,076	0,986	-0,673		Algorithm converged.	-1,292	-0,054	0,276		Algorithm converged.	0,077	0,988	0,0567	0,0424	3,62		Algorithm converged.	1,013	12,943
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE	*	Algorithm not converged.	NE	NE	-2,632		Algorithm converged.	-5,57	0,307	NE	*	Algorithm not converged.	NE	NE	0,2469		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	3,922		Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE		Algorithm not converged.	NE	NE
		Bacteraemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cellulitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Lung abscess	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Osteomyelitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	18-64	1168	87,886	3	0,257	1183	88,814	7	0,592	0,433		Algorithm converged.	0,112	1,677	-0,335		Algorithm converged.	-0,86	0,19	0,434		Algorithm converged.	0,113	1,675	0,3428		2,304		Algorithm converged.	0,597	8,887
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	*	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	3,922	*	Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE		Algorithm not converged.	NE	NE

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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pneumonia bacterial	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Injury, poisoning and procedural complications	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	*	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	*	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Ankle fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	*	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Cervical vertebral fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm not converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fall	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm not converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm not converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Tibia fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm not converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm not converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Investigations	--		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
Weight decreased	--		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
Metabolism and nutrition disorders	--		18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169		Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	3	2,632	0,339		Algorithm converged.	0,035	3,314	-1,722		Algorithm converged.	-5,155	1,71	0,345		Algorithm converged.	0,036	3,271	0,6219		2,895		Algorithm converged.	0,306	27,409
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Dehydration	--		18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Hyperglycaemia	--		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909		Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Hypokalaemia	--		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE *	Algorithm not converged.	NE	NE	-1,754	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013	Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastric cancer		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
Nervous system disorders	--		18-64	1168	87,886	3	0,257	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,257	*	Algorithm converged.	-0,033	0,547	NE	*	Algorithm not converged.	NE	NE	0,1225		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Facial paresis		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Headache	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Syncope	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	18-64	1168	87,886	0	0	1183	88,814	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	9	0,761	0,112	Algorithm converged.	0,014	0,884	-0,675	Algorithm converged.	-1,198	-0,152	0,113		Algorithm converged.	0,014	0,887	0,0212	0,5809	8,886	Algorithm converged.	1,128	70,026
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	4	11,429	NE *	Algorithm not converged.	NE	NE	-11,429	Algorithm converged.	-21,969	-0,888	NE	*	Algorithm not converged.	NE	NE	0,0247		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Acute respiratory distress syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Dyspnoea	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	1168	87,886	1	0,086	1183	88,814	4	0,338	0,253		Algorithm converged.	0,028	2,263	-0,253	Algorithm converged.	-0,623	0,118	0,253		Algorithm converged.	0,028	2,262	0,3745		3,949	Algorithm converged.	0,442	35,281
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pneumothorax spontaneous	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Surgical and medical procedures	--											Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vascular disorders	--											Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		May-Thurner syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37			-0,917		Algorithm converged.	0,038	3,588	0,373		Algorithm converged.	-2,877	1,043	0,951		2,678		Algorithm converged.	0,281	25,52		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951			-0,009		Algorithm converged.	0,059	15,237	0,951		Algorithm converged.	-0,49	0,473	0,951		1,052		Algorithm converged.	0,066	16,773		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Arrhythmia neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	*	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cardiac failure congestive	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	*	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Coronary artery disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	*	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874	NE	Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	<=10^6 copies/mL	370	27.84	1	0.27	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	0.27		Algorithm converged.	-0.259	0.799	NE	*	Algorithm not converged.	NE	NE	1	0.1122	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	157	11.813	0	0	183	13.739	1	0.546	NE	*	Algorithm not converged.	NE	NE	-0.546		Algorithm converged.	-1.615	0.522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk		Relative Risk		Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE	*	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	-1.442	0.466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	5	0.891	NE	*	Algorithm not converged.	NE	NE	-0.891	Algorithm converged.	-1.669	-0.114	NE	*	Algorithm not converged.	NE	NE	0.0273		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE	*	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	-1.442	0.466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Cholecystitis acute	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	1	0.169	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	0.169		Algorithm converged.	-0.162	0.501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	<=10^5 copies/mL	370	27.84	0	0	360	27.027	2	0.556	NE	*	Algorithm not converged.	NE	NE	-0.556		Algorithm converged.	-1.323	0.212	NE	*	Algorithm not converged.	NE	NE	0.2429	0.0811	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	2	1.274	183	13.739	1	0.546	2,348		Algorithm converged.	0.211	26,147	0,727		Algorithm converged.	-1.326	2,781	2,331		Algorithm converged.	0.213	25,466	0.5973		0.429		Algorithm converged.	0.039	4,686
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	5	2.439	NE	*	Algorithm not converged.	NE	NE	-2.439		Algorithm converged.	-4.551	-0.327	NE	*	Algorithm not converged.	NE	NE	0.0629		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	3	0.508	561	42.117	6	1.07	0.473		Algorithm converged.	0.118	1,899	-0.561		Algorithm converged.	-1.588	0.466	0.475		Algorithm converged.	0.119	1,892	0.3308		2,103		Algorithm converged.	0.529	8.37
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bacteraemia	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cellulitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488		Algorithm not converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278		Algorithm not converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lung abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	0,27	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	2	1,274	183	13,739	1	0,546	2,348		Algorithm converged.	0,211	26,147	0,727		Algorithm converged.	-1,326	2,781	2,331		Algorithm converged.	0,213	25,466	0,5973		0,429	Algorithm converged.	0,039	4,686
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463		Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^7 copies/mL	590	44.394	3	0.508	561	42.117	5	0.891	0.568	Algorithm not converged.	0.135	2.389	-0.383	Algorithm not converged.	-1.349	0.584	0.571	Algorithm converged.	0.137	2.376	0.4964		1.753	Algorithm converged.	0.421	7.3		
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE *	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	-1.442	0.466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE *	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	-1.442	0.466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	<=10^5 copies/mL	370	27.84	0	0	360	27.027	1	0.278	NE *	Algorithm not converged.	NE	NE	-0.278	Algorithm converged.	-0.821	0.266	NE *	Algorithm not converged.	NE	NE	0.4932		NE	Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ankle fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	*	Algorithm not converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tibia fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk													
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Investigations	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	1	0.169	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	0.169		Algorithm not converged.	-0.162	0.501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	1	0.169	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	0.169		Algorithm not converged.	-0.162	0.501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27.84	1	0.27	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	0.27		Algorithm converged.	-0.259	0.799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	1	0.546	NE	*	Algorithm not converged.	NE	NE	-0.546		Algorithm converged.	-1.615	0.522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL	590	44.394	0	0	561	42.117	4	0.713	NE	*	Algorithm not converged.	NE	NE	-0.713	Algorithm converged.	-1.409	-0.017	NE	*	Algorithm not converged.	NE	NE	0.0561		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	<=10^5 copies/mL	370	27.84	1	0.27	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	0.27	Algorithm converged.	-0.259	0.799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	1	0.546	NE	*	Algorithm not converged.	NE	NE	-0.546	Algorithm converged.	-1.615	0.522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Hyponatraemia	<=10^5 copies/mL	370	27.84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	NE	NE	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Type 2 diabetes mellitus	<=10^5 copies/mL	370	27.84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	370	27.84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	NE	NE	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	NE	NE	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Intervertebral disc protrusion	<=10^5 copies/mL	370	27.84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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ENDPOINT: AEs Grade >= 3 (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE *	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,339	Algorithm converged.	-0,13	0,808	NE *	Algorithm not converged.	NE	NE	0,4999		NE		Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Facial paresis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE *	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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ENDPOINT: AEs Grade >= 3 (excluding disease related events)

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Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
		Syncope	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	NE	NE	0,169	*	Algorithm not converged.	NE	NE	1	*	Algorithm not converged.	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
		Anxiety	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE

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Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,237	-0,009	Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,773	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Nephrolithiasis	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	1	0.169	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	0.169		Algorithm not converged.	-0.162	0.501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE	*	Algorithm not converged.	NE	NE	-0.488		Algorithm not converged.	-1.442	0.466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	370	27.84	1	0.27	360	27.027	1	0.278	0.973		Algorithm converged.	0.061	15.614	-0.008		Algorithm converged.	-0.766	0.751	0.973		Algorithm converged.	0.061	15.496	1	0.2093	1.028		Algorithm converged.	0.065	16.369
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	1	0.546	NE	*	Algorithm not converged.	NE	NE	-0.546		Algorithm converged.	-1.615	0.522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	3	1.463	NE	*	Algorithm not converged.	NE	NE	-1.463		Algorithm converged.	-3.107	0.18	NE	*	Algorithm not converged.	NE	NE	0.2505		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	9	1.604	NE	*	Algorithm not converged.	NE	NE	-1.604		Algorithm converged.	-2.644	-0.565	NE	*	Algorithm not converged.	NE	NE	0.0015		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Acute respiratory distress syndrome	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE *	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	NE	NE	0.466	NE *	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE *	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	NE	NE	0.466	NE *	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	2	0.357	NE *	Algorithm not converged.	NE	NE	-0.357	Algorithm converged.	NE	NE	0.137	NE *	Algorithm not converged.	NE	NE	0.2373		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE *	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	NE	NE	0.171	NE *	Algorithm not converged.	NE	NE	0.4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Dyspnoea	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE *	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE *	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE *	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE *	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE *	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hospitalisation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Country	Cardiac disorders	--	USA	1237	93,078	2	0,162	1239	93,018	4	0,323	0,5	Algorithm converged.	0,091	2,735	-0,161	Algorithm converged.	-0,548	0,226	0,501	Algorithm converged.	0,092	2,729	0,6871	1	1,997	Algorithm converged.	0,366	10,882	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Arrhythmia neonatal		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Atrial fibrillation		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Cardiac failure congestive		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Coronary artery disease		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Tachycardia		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Gastrointestinal disorders	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	1237	93,078	1	0,081	1239	93,018	5	0,404	0,2		Algorithm converged.	0,023	1,712	-0,323		Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	0,4316	4,992		Algorithm converged.	0,584	42,666
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Death	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fever neonatal	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	USA	1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998		Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pyrexia	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatobiliary disorders	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Infections and infestations	USA	1237	93,078	5	0,404	1239	93,018	14	1,13	0,355	Algorithm converged.	0,128	0,989	-0,726	Algorithm converged.	-1,412	-0,039	0,358	Algorithm converged.	0,129	0,99	0,0626	1	2,795	Algorithm converged.	1,01	7,737
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Bacteraemia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cellulitis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastroenteritis		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Lung abscess		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Osteomyelitis acute		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pneumonia		USA	1237	93,078	5	0,404	1239	93,018	9	0,726	0,555		Algorithm converged.	0,185	1,66	-0,322		Algorithm converged.	-0,913	0,268	0,556		Algorithm converged.	0,187	1,656	0,4226	1	1,797		Algorithm converged.	0,604	5,347
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pneumonia bacterial		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pneumonia viral		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Sepsis		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Injury, poisoning and procedural complications		--	USA	1237	93,078	3	0,243	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,243	Algorithm converged.	-0,032	0,517	NE *	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Ankle fracture			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Cervical vertebral fracture			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Fall			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Spinal compression fracture			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Tibia fracture			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Upper limb fracture			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Investigations	--		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Weight decreased			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Metabolism and nutrition disorders	--		USA	1237	93,078	1	0,081	1239	93,018	5	0,404	0,2		Algorithm converged.	0,023	1,712	-0,323	Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	1	4,992	Algorithm converged.	0,584	42,666
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Dehydration			USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hyperglycaemia			USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hypokalaemia			USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hyponatraemia			USA	1237	93,078	0	0	1239	93,018	2	0,161	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Type 2 diabetes mellitus	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Musculoskeletal and connective tissue disorders	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastric cancer	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nervous system disorders	USA	1237	93,078	3	0,243	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,243	Algorithm converged.	-0,032	0,517	NE *	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Facial paresis		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Headache		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Syncope		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998		Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Anxiety		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Depression		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5		Algorithm converged.	0,045	5,526	-0,081		Algorithm converged.	-0,355	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997		Algorithm converged.	0,181	21,992
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Acute kidney injury	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Nephrolithiasis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Renal failure	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,078	1	0,081	1239	93,018	13	1,049	0,076		Algorithm converged.	0,01	0,584	-0,968	Algorithm converged.	-1,557	-0,379	0,077		Algorithm converged.	0,01	0,588	0,0018	0,7064	12,979	Algorithm converged.	1,7	99,063
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
		Acute respiratory failure	USA	1237	93,078	0	0	1239	93,018	3	0,242	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,516	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Chronic obstructive pulmonary disease	USA		1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Dyspnoea	USA		1237	93,078	0	0	1239	93,018	4	0,323	NE	*	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,639	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hypoxia	USA		1237	93,078	1	0,081	1239	93,018	5	0,404	0,2		Algorithm converged.	0,023	1,712	-0,323	Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	1	4,992	Algorithm converged.	0,584	42,666	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Pneumothorax spontaneous	USA		1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Pulmonary mass	USA		1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Surgical and medical procedures	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hospitalisation	USA		1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade >= 3 (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Vascular disorders	--		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
May-Thurner syndrome			USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Cardiac disorders	--	--	1329	100	1	0,075	1332	100	3	0,225	0,334	Algorithm converged.	0,035	3,211	-0,15	Algorithm converged.	-0,444	0,144	0,334	Algorithm converged.	0,035	3,208	0,6247		2,993	Algorithm converged.	0,312	28,739	
		Arrhythmia neonatal	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tachycardia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	4	0,3	0,25	Algorithm converged.	0,028	2,24	-0,225	Algorithm converged.	-0,554	0,104	0,251	Algorithm converged.	0,028	2,239	0,3745		3,991	Algorithm converged.	0,447	35,66		
	Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935		
	Pyrexia	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
Hepatobiliary disorders	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	Hyperbilirubinaemia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
Infections and infestations	--	--	1329	100	9	0,677	1332	100	23	1,727	0,388	Algorithm converged.	0,179	0,842	-1,05	Algorithm converged.	-1,876	-0,223	0,392	Algorithm converged.	0,182	0,844	0,013		2,55	Algorithm converged.	1,184	5,49		
	Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
	COVID-19	--	1329	100	3	0,226	1332	100	6	0,45	0,5	Algorithm converged.	0,125	2,003	-0,225	Algorithm converged.	-0,666	0,216	0,501	Algorithm converged.	0,126	2	0,5071		1,995	Algorithm converged.	0,5	7,962		
	COVID-19 pneumonia	--	1329	100	2	0,15	1332	100	5	0,375	0,4	Algorithm converged.	0,077	2,065	-0,225	Algorithm converged.	-0,614	0,164	0,401	Algorithm converged.	0,078	2,063	0,4525		2,494	Algorithm converged.	0,485	12,834		
	Cellulitis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	5	0,376	1332	100	8	0,601	0,625		Algorithm converged.	0,204	1,915	-0,224	Algorithm converged.	-0,754	0,305	0,626		Algorithm converged.	0,205	1,91	0,5801		1,596	Algorithm converged.	0,524	4,867
		Pneumonia bacterial	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Injury, poisoning and procedural complications	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Investigations	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643
		Dehydration	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyponatraemia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	*	Algorithm not converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	*	Algorithm not converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	0	0	1332	100	11	0,826	NE	*	Algorithm not converged.	NE	NE	-0,826	Algorithm converged.	-1,312	-0,34	NE	*	Algorithm not converged.	NE	NE	0,001		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hypoxia	--	1329	100	0	0	1332	100	5	0,375	NE	*	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE	*	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	5	0,376	1332	100	8	0,601	0,625		Algorithm converged.	0,204	1,915	-0,224	Algorithm converged.	-0,754	0,305	0,626		Algorithm converged.	0,205	1,91	0,5801		1,596	Algorithm converged.	0,524	4,867
		Pneumonia bacterial	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Injury, poisoning and procedural complications	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Investigations	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Weight decreased	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	--	1329	100	1	0,075	1332	100	5	0,375	0,2		Algorithm converged.	0,023	1,713	-0,3	Algorithm converged.	-0,66	0,06	0,2		Algorithm converged.	0,023	1,713	0,2182		4,989	Algorithm converged.	0,584	42,643
		Dehydration	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyponatraemia	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	*	Algorithm not converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Intervertebral disc protrusion	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	--	1329	100	3	0,226	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,226	Algorithm converged.	-0,029	0,481	NE	*	Algorithm not converged.	NE	NE	0,1244		NE	Algorithm not converged.	NE	NE
		Facial paresis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Headache	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Syncope	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	*	Algorithm not converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Anxiety	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Depression	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	0	0	1332	100	11	0,826	NE	*	Algorithm not converged.	NE	NE	-0,826	Algorithm converged.	-1,312	-0,34	NE	*	Algorithm not converged.	NE	NE	0,001		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	4	0,3	NE	*	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hypoxia	--	1329	100	0	0	1332	100	5	0,375	NE	*	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE	*	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Sex	Cardiac disorders	--	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm not converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1	0,0346	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
	Arrhythmia neonatal		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Atrial fibrillation		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Cardiac failure congestive		Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation		Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	0,2721	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507	Algorithm converged.	0,046	5,599	-0,141	Algorithm converged.	-0,629	0,347	0,507	Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69		
		Fever neonatal	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Non-cardiac chest pain	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015	Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015	Algorithm converged.	0,064	16,187	1		0,986	Algorithm converged.	0,062	15,727		
		Pyrexia	Male	641	48,232	0	0	634	47,598	2	0,315	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE *	Algorithm not converged.	NE	NE	0,2471	NE	NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Hepatobiliary disorders	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Hyperbilirubinaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		Infections and infestations	Male	641	48,232	8	1,248	634	47,598	13	2,05	0,604	Algorithm converged.	0,249	1,467	-0,802	Algorithm converged.	-2,201	0,596	0,609	Algorithm converged.	0,254	1,458	0,2605	0,0679	1,643	Algorithm converged.	0,686	3,937		
			Female	688	51,768	1	0,145	698	52,402	10	1,433	0,1	Algorithm converged.	0,013	0,784	-1,287	Algorithm converged.	-2,214	-0,361	0,101	Algorithm converged.	0,013	0,79	0,0114		9,857	Algorithm converged.	1,265	76,791		
		Bacteraemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE		
		COVID-19	Male	641	48,232	3	0,468	634	47,598	4	0,631	0,741	Algorithm converged.	0,165	3,322	-0,163	Algorithm converged.	-0,975	0,649	0,742	Algorithm converged.	0,167	3,301	0,7244	0,172	1,348	Algorithm converged.	0,303	5,999		

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	Male	641	48,232	2	0,312	634	47,598	3	0,473	0,658		Algorithm converged.	0,11	3,953	-0,161	Algorithm converged.	-0,848	0,526	0,659		Algorithm converged.	0,111	3,933	0,6853	0,2033	1,517	Algorithm converged.	0,254	9,046	
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Cellulitis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Gastroenteritis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Lung abscess	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	Male	641	48,232	4	0,624	634	47,598	4	0,631	0,989		Algorithm converged.	0,246	3,972	-0,007	Algorithm converged.	-0,874	0,86	0,989		Algorithm converged.	0,248	3,938	1	0,2759	1,011	Algorithm converged.	0,254	4,025	
			Female	688	51,768	1	0,145	698	52,402	4	0,573	0,253		Algorithm converged.	0,028	2,265	-0,428	Algorithm converged.	-1,056	0,2	0,254		Algorithm converged.	0,028	2,263	0,3742		3,943	Algorithm converged.	0,442	35,186	
		Pneumonia bacterial	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Pneumonia viral	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Sepsis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Injury, poisoning and procedural complications	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	3	0,436	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,436	Algorithm converged.	-0,056	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE	Algorithm not converged.	NE	NE	
		Ankle fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Cervical vertebral fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Fall	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Spinal compression fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Tibia fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
	Investigations	--	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Weight decreased	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002		Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	0,1067	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	4	0,573	NE	*	Algorithm not converged.	NE	NE	-0,573		Algorithm converged.	-1,133	-0,013	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE
		Dehydration	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hyponatraemia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989		Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989		Algorithm converged.	0,062	15,779	1	1	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Nervous system disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	3	0,436	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,436	Algorithm converged.	-0,056	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE	Algorithm not converged.	NE	NE
		Facial paresis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Headache	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Syncope	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	NE
	Psychiatric disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002		Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,187	1		0,986		Algorithm converged.	0,062	15,727	
		Anxiety	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	NE
		Depression	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE
	Renal and urinary disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
		Acute kidney injury	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	641	48,232	0	0	634	47,598	9	1,42	NE	*	Algorithm not converged.	NE	NE	-1,42		Algorithm converged.	-2,34	-0,499	NE	*	Algorithm not converged.	NE	NE	0,0018	1	NE		Algorithm not converged.	NE	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).

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95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Acute respiratory distress syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Dyspnoea	Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Hypoxia	Male	641	48,232	0	0	634	47,598	5	0,789	NE	*	Algorithm not converged.	NE	NE	-0,789	Algorithm converged.	-1,477	-0,1	NE	*	Algorithm not converged.	NE	NE	0,0302	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Hospitalisation	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Vascular disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

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If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Age	Cardiac disorders	--	18-64	1168	87,886	0	0	1183	88,81	2	0,169	NE *	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Tachycardia		18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Gastrointestinal disorders	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	1168	87,886	1	0,086	1183	88,81	4	0,338	0,253	Algorithm converged.	0,028	2,263	-0,253		Algorithm converged.	-0,623	0,118	0,253		Algorithm converged.	0,028	2,262	0,3745		3,949	Algorithm converged.	0,442	35,281
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Fever neonatal	--	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain	--	18-64	1168	87,886	1	0,086	1183	88,81	1	0,085	1,013	Algorithm converged.	0,063	16,21	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo							Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pyrexia	18-64	1168	87,886	0	0	1183	88,81	2	0,169	NE *	Algorithm not converged.	NE	NE	-0,169	Algorithm not converged.	-0,403	0,065	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperbilirubinaemia	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	18-64	1168	87,886	5	0,428	1183	88,81	15	1,268	0,335	Algorithm converged.	0,121	0,924	-0,84	Algorithm converged.	-1,579	-0,1	0,338	Algorithm converged.	0,123	0,926	0,0406	0,8069	2,962	Algorithm converged.	1,08	8,123
			65-74	110	8,277	2	1,818	114	8,559	6	5,263	0,333	Algorithm converged.	0,066	1,688	-3,445	Algorithm converged.	-8,245	1,355	0,345	Algorithm converged.	0,071	1,675	0,2808		2,895	Algorithm converged.	0,597	14,036
			>=75	51	3,837	2	3,922	35	2,628	2	5,714	0,673	Algorithm converged.	0,09	5,022	-1,793	Algorithm converged.	-11,15	7,562	0,686	Algorithm converged.	0,101	4,645	1		1,457	Algorithm converged.	0,215	9,862
		Bacteraemia	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		COVID-19	18-64	1168	87,886	2	0,171	1183	88,81	3	0,254	0,675	Algorithm converged.	0,113	4,045	-0,082	Algorithm converged.	-0,454	0,29	0,675	Algorithm converged.	0,113	4,034	1	0,5464	1,481	Algorithm converged.	0,248	8,847
			65-74	110	8,277	1	0,909	114	8,559	2	1,754	0,514	Algorithm converged.	0,046	5,748	-0,845	Algorithm converged.	-3,838	2,147	0,518	Algorithm converged.	0,048	5,633	1		1,93	Algorithm converged.	0,178	20,98
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	18-64	1168	87,886	0	0	1183	88,81	2	0,169	NE *	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	2	1,818	114	8,559	2	1,754	1,037	Algorithm converged.	0,144	7,494	0,064	Algorithm converged.	-3,406	3,534	1,036	Algorithm converged.	0,149	7,229	1		0,965	Algorithm converged.	0,138	6,731
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Cellulitis	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Lung abscess	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Osteomyelitis acute	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	18-64	1168	87,886	3	0,257	1183	88,81	6	0,507	0,505	Algorithm converged.	0,126	2,025	-0,25	Algorithm converged.	-0,748	0,248	0,506		Algorithm converged.	0,127	2,02	0,5071	0,082	1,975	Algorithm converged.	0,495	7,877
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE *	Algorithm not converged.	NE	NE	-1,754	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	2	3,922	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	3,922	Algorithm converged.	-1,406	9,249	NE	*	Algorithm not converged.	NE	NE	0,5116		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Sepsis	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Injury, poisoning and procedural complications	--	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
				65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
				>=75	51	3,837	1	1,961	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Ankle fracture	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
				65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
				>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
				65-74	110	8,277	1	0,909	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE *	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE
				>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
				65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
				>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Spinal compression fracture	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Tibia fracture	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Weight decreased	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Metabolism and nutrition disorders	--		18-64	1168	87,886	0	0	1183	88,81	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	3	2,632	0,339			0,035	3,314	-1,722	Algorithm converged.	-5,155	1,71	0,345	Algorithm converged.	0,036	3,271	0,6219		2,895	Algorithm converged.	0,306	27,409		
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Dehydration		18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hyperglycaemia		18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hypokalaemia		18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hyponatraemia		18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Type 2 diabetes mellitus	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	1168	87,886	1	0,086	1183	88,81	1	0,085	1,013	Algorithm converged.	0,063	16,21	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,17	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nervous system disorders	18-64	1168	87,886	3	0,257	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,257	Algorithm converged.	-0,033	0,547	NE *	Algorithm not converged.	NE	NE	0,1225		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Facial paresis	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Headache	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Syncope	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	18-64	1168	87,886	1	0,086	1183	88,81	1	0,085	1,013	Algorithm converged.	0,063	16,21	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,17	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
Name	SOC	PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Depression	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	1168	87,886	0	0	1183	88,81	9	0,761	NE	*	Algorithm not converged.	NE	NE	-0,761	*	Algorithm converged.	-1,256	-0,266	NE	*	Algorithm not converged.	NE	NE	0,0039		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
		Acute respiratory failure	18-64	1168	87,886	0	0	1183	88,81	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	18-64	1168	87,886	0	0	1183	88,81	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Hypoxia	18-64	1168	87,886	0	0	1183	88,81	4	0,338	NE	*	Algorithm not converged.	NE	NE	-0,338	Algorithm converged.	-0,669	-0,007	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
	Vascular disorders	--	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951		Algorithm converged.	0,059	15,24	-0,009		Algorithm converged.	-0,49	0,473	0,951		Algorithm converged.	0,06	15,165	1		1,052		Algorithm converged.	0,066	16,77
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Arrhythmia neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cardiac failure congestive	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tachycardia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm not converged.	NE	NE	0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
	General disorders and administration site conditions	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	NE	NE	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	NE	NE	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	NE	NE	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	NE	NE	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Fever neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	NE	NE	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Non-cardiac chest pain	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	NE	NE	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Pyrexia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Hepatobiliary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Hyperbilirubinaemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Infections and infestations	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	3	0,833	NE	*	Algorithm not converged.	NE	NE	-0,833	Algorithm converged.	-1,772	0,106	NE	*	Algorithm not converged.	NE	NE	0,1194	0,0406	NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	2	1,274	183	13,739	1	0,546	2,348		Algorithm converged.	0,211	26,15	0,727	Algorithm converged.	-1,326	2,781	2,331		Algorithm converged.	0,213	25,466	0,5973		0,429	Algorithm converged.	0,039	4,686		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	6	2,927	NE	*	Algorithm not converged.	NE	NE	-2,927	Algorithm converged.	-5,234	-0,619	NE	*	Algorithm not converged.	NE	NE	0,0315		NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	7	1,186	561	42,117	13	2,317	0,506		Algorithm converged.	0,2	1,278	-1,131	Algorithm converged.	-2,652	0,39	0,512		Algorithm converged.	0,206	1,274	0,1424		1,953	Algorithm converged.	0,785	4,86		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Bacteraemia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
				>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
				>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
				>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
				Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			COVID-19	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
				>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
				>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
				>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	4	0,713	0,712		Algorithm converged.	0,159	3,194	-0,205	Algorithm converged.	-1,107	0,698	0,713		Algorithm converged.	0,16	3,172	0,7194		1,402	Algorithm converged.	0,315	6,237	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19 pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976		Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	3	0,535	0,633		Algorithm converged.	0,105	3,8	-0,196		Algorithm converged.	-0,96	0,569	0,634		Algorithm converged.	0,106	3,779	0,6794		1,578		Algorithm converged.	0,265	9,406
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cellulitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Gastroenteritis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Lung abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Osteomyelitis acute	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	2	1,274	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	1,274	Algorithm converged.	-0,48	3,028	NE	*	Algorithm not converged.	NE	NE	0,2125		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463	Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	3	0,508	561	42,117	5	0,891	0,568		Algorithm converged.	0,135	2,389	-0,383	Algorithm converged.	-1,349	0,584	0,571		Algorithm converged.	0,137	2,376	0,4964		1,753	Algorithm converged.	0,421	7,3	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia bacterial	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ankle fracture	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,522	1,615	NE *	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tibia fracture	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk												
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE			
		Upper limb fracture	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Investigations	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Weight decreased	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	4	0,713	NE	*	Algorithm not converged.	NE	NE	-0,713	Algorithm converged.	-1,409	-0,017	NE	*	Algorithm not converged.	NE	NE	0,0561		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyperglycaemia	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np < =5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo											Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk																
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL											
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
		Intervertebral disc protrusion	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Rhabdomyolysis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Nervous system disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,339		Algorithm converged.	-0,13	0,808	NE	*	Algorithm not converged.	NE	NE	0,4999		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Facial paresis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Syncope	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	1	0,178	0,951	Algorithm converged.	0,059	15,24	-0,009	Algorithm converged.	-0,49	0,473	0,951	Algorithm converged.	0,06	15,165	1		1,052	Algorithm converged.	0,066	16,77		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Anxiety	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE	*	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^7 copies/mL	590	44,394	0	0	561	42,117	7	1,248	NE	*	Algorithm not converged.	NE	NE	-1,248		Algorithm not converged.	-2,166	-0,329	NE	*	Algorithm not converged.	NE	NE	0,0064		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm not converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm not converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dyspnoea	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm not converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm not converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm not converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE	*	Algorithm not converged.	NE	NE	-0,535		Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hospitalisation	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

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95% CI for the relative risk use Farrington-Manning method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Vascular disorders	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0.178	NE *	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0.178	NE *	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Cardiac disorders	--	USA	1237	93,08	1	0,08	1239	93,02	3	0,24	0,333	Algorithm converged.	0,035	3,209	-0,161	Algorithm converged.	-0,48	0,155	0,334	Algorithm converged.	0,035	3,205	0,6247	1	2,995	Algorithm converged.	0,312	28,76		
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
General disorders and administration site conditions	--		USA	1237	93,08	1	0,08	1239	93,02	4	0,32	0,25	Algorithm converged.	0,028	2,238	-0,242	Algorithm converged.	-0,6	0,111	0,25	Algorithm converged.	0,028	2,237	0,3745	1	3,994	Algorithm converged.	0,447	35,68
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
Fever neonatal			USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
Non-cardiac chest pain			USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
Pyrexia			USA	1237	93,08	0	0	1239	93,02	2	0,16	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
Hepatobiliary disorders	--		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
Hyperbilirubinaemia			USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.
Infections and infestations	--		USA	1237	93,08	7	0,57	1239	93,02	20	1,61	0,347	Algorithm converged.	0,146	0,823	-1,048	Algorithm converged.	-1,87	-0,23	0,351	Algorithm converged.	0,149	0,826	0,012	0,5217	2,853	Algorithm converged.	1,211	6,722
			MEX	92	6,922	2	2,17	93	6,982	3	3,23	0,667	Algorithm converged.	0,109	4,085	-1,052	Algorithm converged.	-5,72	3,614	0,674	Algorithm converged.	0,115	3,94	1		1,484	Algorithm converged.	0,254	8,675

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test p-value (likelihood ratio)	Relative Risk	Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value			Convergence Reason	95% Lower CL	95% upper CL				
		Bacteraemia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19	USA	1237	93,08	1	0,08	1239	93,02	3	0,24	0,333		Algorithm converged.	0,035	3,209	-0,161	Algorithm converged.	-0,48	0,155	0,334		Algorithm converged.	0,035	3,205	0,6247	0,6262	2,995		Algorithm converged.	0,312	28,76
			MEX	92	6,922	2	2,17	93	6,982	3	3,23	0,667		Algorithm converged.	0,109	4,085	-1,052	Algorithm converged.	-5,72	3,614	0,674		Algorithm converged.	0,115	3,94	1		1,484		Algorithm converged.	0,254	8,675
		COVID-19 pneumonia	USA	1237	93,08	2	0,16	1239	93,02	5	0,4	0,4		Algorithm converged.	0,077	2,064	-0,242	Algorithm converged.	-0,66	0,176	0,401		Algorithm converged.	0,078	2,061	0,4525	1	2,496		Algorithm converged.	0,485	12,84
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cellulitis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastroenteritis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Lung abscess	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Osteomyelitis acute	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	USA	1237	93,08	5	0,4	1239	93,02	8	0,65	0,624		Algorithm converged.	0,204	1,914	-0,241		Algorithm converged.	-0,81	0,328	0,626		Algorithm converged.	0,205	1,908	0,58	1	1,597		Algorithm converged.	0,524	4,869
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia bacterial	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia viral	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Injury, poisoning and procedural complications	USA	1237	93,08	3	0,24	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,243		Algorithm converged.	-0,03	0,517	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ankle fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cervical vertebral fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE

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ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fall	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Spinal compression fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tibia fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Investigations	--	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Weight decreased	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	1237	93,08	1	0,08	1239	93,02	5	0,4	0,2		Algorithm converged.	0,023	1,712	-0,323		Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	1	4,992		Algorithm converged.	0,584	42,67

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyperglycaemia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Type 2 diabetes mellitus	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Intervertebral disc protrusion	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Nervous system disorders	--	USA	1237	93,08	3	0,24	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,243		Algorithm converged.	-0,03	0,517	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Facial paresis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Headache	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Syncope	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Anxiety	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Depression	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute kidney injury	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,08	0	0	1239	93,02	11	0,89	NE	*	Algorithm not converged.	NE	NE	-0,888	Algorithm converged.	-1,41	-0,37	NE	*	Algorithm not converged.	NE	NE	0,001		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory distress syndrome	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	USA	1237	93,08	0	0	1239	93,02	4	0,32	NE	*	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,64	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 3

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	1237	93,08	0	0	1239	93,02	5	0,4	NE	*	Algorithm not converged.	NE	NE	-0,404		Algorithm converged.	-0,76	-0,05	NE	*	Algorithm not converged.	NE	NE	0,0622		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo				Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference		Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	Cardiac disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,01	1		0,998	Algorithm converged.	0,062	15,94
		Acute myocardial infarction	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Hepatobiliary disorders	Cholecystitis acute	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Infections and infestations	COVID-19 pneumonia	--	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Renal and urinary disorders	Nephrolithiasis	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,01	1		0,998	Algorithm converged.	0,062	15,94
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk			
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Sex	Cardiac disorders	--	Male	641	48,232	1	0,156	634	47,598	1	0,158	0,989	Algorithm converged.	0,062	15,847	-0,002	Algorithm converged.	-0,436	0,433	0,989	Algorithm converged.	0,062	15,779	1	1	1,011	Algorithm converged.	0,063	16,129
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cholecystitis acute		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	Male	641	48,232	0	0	634	47,598	2	0,315	NE *	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE *	Algorithm not converged.	NE	NE	0,2471	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE *	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE *	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
	COVID-19		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	COVID-19 pneumonia		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Pneumonia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0943	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Renal failure	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Age	Cardiac disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE	
	Acute myocardial infarction		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Coronary artery disease		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE	
	Hepatobiliary disorders	--	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Cholecystitis acute		18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	infections and infestations	--	18-64	1168	87,886	0	0	1183	88,814	2	0,169	NE	*	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab														
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	*	Algorithm not converged.	NE	NE	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		COVID-19	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm not converged.	NE	NE	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	*	Algorithm not converged.	NE	NE	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		Pneumonia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm not converged.	NE	NE	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Renal and urinary disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm not converged.	NE	NE	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm not converged.	NE	NE	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm not converged.	NE	NE	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Renal failure	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714		Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,55	205	15,39	1	0,49	1,121		Algorithm converged.	0,07	18,05	0,059		Algorithm converged.	-1,37	1,491	1,12		Algorithm converged.	0,071	17,78	1		0,893		Algorithm converged.	0,056	14,17
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,55	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,52	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Coronary artery disease	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

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Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
	Hepatobiliary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE							
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE							
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
		Cholecystitis acute	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE							
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
	Infections and infestations	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE							
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,98	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,32	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003	NE	NE	NE	NE	NE							
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE							
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE							

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POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		COVID-19	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		COVID-19 pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab															
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk																			
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL														
	Renal and urinary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE				
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE			
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			Nephrolithiasis	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
				Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Renal failure	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
				Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE			NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk						Relative Risk											
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL								
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE							
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
		Acute respiratory failure	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE							
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
		Pneumothorax spontaneous	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE							
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE						

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab		Placebo		Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Country	Cardiac disorders	--	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002	Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		USA	1237	93,078	1	0,081	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996	NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Coronary artery disease		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Cholecystitis acute		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	USA	1237	93,078	0	0	1239	93,018	2	0,161	NE *	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998	NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE *	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973	NE	Algorithm not converged.	NE	NE	
	COVID-19		USA	1237	93,078	0	0	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	COVID-19 pneumonia		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,078	1	0,081	1239	93,018	1	0,081	1,002		Algorithm converged.	0,063	16,031	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	15,995	1	1	0,998	Algorithm converged.	0,063	15,944
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	USA	1237	93,078	0	0	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 4

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			MEX	92	6,922	0	0	93	6,982	1	1,075	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk		Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
All	General disorders and administration site conditions	--	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
	Death	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Multiple organ dysfunction syndrome	--	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	COVID-19	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastric cancer	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	1	0,075	1332	100	2	0,15	0,501		Algorithm converged.	0,045	5,529	-0,075	Algorithm converged.	-0,33	0,18	0,501		Algorithm converged.	0,045	5,52	1		1,995	Algorithm converged.	0,181	21,98
	Chronic obstructive pulmonary disease	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hypoxia	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Pulmonary mass	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Sex	General disorders and administration site conditions	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,92	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE	
	Death		Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Multiple organ dysfunction syndrome		Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	2	0,29	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,68	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
	Infections and infestations	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	COVID-19		Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Gastric cancer	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	641	48,23	1	0,16	634	47,6	1	0,16	0,989	Algorithm converged.	0,062	15,85	-0,002	Algorithm converged.	-0,44	0,433	0,989	Algorithm converged.	0,062	15,78	1	0,3101	1,011	Algorithm converged.	0,063	16,13
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hypoxia	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Age	General disorders and administration site conditions	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,85	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	NE	NE	
	Death		18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	NE	NE	
	Multiple organ dysfunction syndrome		18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,4	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE	NE	NE	
	Infections and infestations	--	18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	COVID-19		18-64	1168	87,886	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory, thoracic and mediastinal disorders	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	*	Algorithm converged.	-13,4	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	18-64	1168	87,886	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Hypoxia	18-64	1168	87,886	1	0,086	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	18-64	1168	87,886	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE *	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE *	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
		PT	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Baseline viral load categories	General disorders and administration site conditions	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	3	0.535	NE	*	Algorithm not converged.	NE	NE	-0.535	Algorithm converged.	-1.138	0.069	NE	*	Algorithm not converged.	NE	NE	0.1155	NE	NE	NE	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Death	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874	NE	NE	NE	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Multiple organ dysfunction syndrome	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	2	0.357	NE	*	Algorithm not converged.	NE	NE	-0.357	Algorithm converged.	-0.85	0.137	NE	*	Algorithm not converged.	NE	NE	0.2373	NE	NE	NE	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
	Infections and infestations	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE	*	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	-1.442	0.466	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		COVID-19	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE	*	Algorithm not converged.	NE	NE	-0.488	Algorithm converged.	-1.442	0.466	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178	Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874	NE	NE	NE	NE	NE
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
		Gastric cancer	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	370	27.84	1	0.27	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	0.27		Algorithm converged.	-0.259	0.799	NE	*	Algorithm not converged.	NE	NE	1	NE	NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	1	0.488	NE	*	Algorithm not converged.	NE	NE	-0.488		Algorithm converged.	-1.442	0.466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
		Chronic obstructive pulmonary disease	<=10^5 copies/mL	370	27.84	0	0	360	27.027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11.813	0	0	183	13.739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13.77	0	0	205	15.39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	590	44.394	0	0	561	42.117	1	0.178	NE	*	Algorithm not converged.	NE	NE	-0.178		Algorithm converged.	-0.527	0.171	NE	*	Algorithm not converged.	NE	NE	0.4874		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	
			Unknown	29	2.182	0	0	23	1.727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Hypoxia	<=10^5 copies/mL	370	27.84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
		Pulmonary mass	<=10^5 copies/mL	370	27.84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	General disorders and administration site conditions	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE *	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
	Death		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Multiple organ dysfunction syndrome		USA	1237	93,078	0	0	1239	93,018	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	2	2,151	NE *	Algorithm not converged.	NE	NE	-2,151	Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
	Infections and infestations	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	COVID-19		USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: AEs Grade 5

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Gastric cancer	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,078	1	0,081	1239	93,018	2	0,161	0,5		Algorithm converged.	0,045	5,526	-0,081	Algorithm converged.	-0,355	0,193	0,501		Algorithm converged.	0,045	5,516	1	1	1,997	Algorithm converged.	0,181	21,992	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	USA	1237	93,078	1	0,081	1239	93,018	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	USA	1237	93,078	0	0	1239	93,018	1	0,081	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
All	Cardiac disorders	--	--	1329	100	3	0,226	1332	100	4	0,3	0,751	Algorithm converged.	0,168	3,363	-0,075	Algorithm converged.	-0,464	0,315	0,752	Algorithm converged.	0,169	3,352	1		1,33	Algorithm converged.	0,298	5,932
	Acute myocardial infarction	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm not converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Angina pectoris	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm not converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Cardiac failure congestive	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm not converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Coronary artery disease	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Tachycardia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Nausea	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Peptic ulcer perforation	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vomiting	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	6	0,45	0,166	Algorithm converged.	0,02	1,384	-0,375	Algorithm converged.	-0,764	0,013	0,167	Algorithm converged.	0,02	1,386	0,1245		5,986	Algorithm converged.	0,722	49,657
	Death	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Fever neonatal	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Multiple organ dysfunction syndrome	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
	Non-cardiac chest pain	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
	Pyrexia	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cholecystitis acute	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Infections and infestations	--	--	1329	100	10	0,752	1332	100	33	2,477	0,298	Algorithm converged.	0,146	0,608	-1,725	Algorithm converged.	-2,68	-0,77	0,304	Algorithm converged.	0,15	0,614	0,0004		3,293	Algorithm converged.	1,629	6,653
	Bacteraemia	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Breast abscess	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	COVID-19 pneumonia	--	--	1329	100	3	0,226	1332	100	11	0,826	0,272	Algorithm converged.	0,076	0,976	-0,6	Algorithm converged.	-1,149	-0,051	0,273	Algorithm converged.	0,076	0,978	0,0567		3,658	Algorithm converged.	1,023	13,084
	Clostridium difficile colitis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastroenteritis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Kidney infection	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Lung abscess	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pneumonia	--	--	1329	100	3	0,226	1332	100	11	0,826	0,272	Algorithm converged.	0,076	0,976	-0,6	Algorithm converged.	-1,149	-0,051	0,273	Algorithm converged.	0,076	0,978	0,0567		3,658	Algorithm converged.	1,023	13,084
	Pneumonia viral	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Sepsis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	--	1329	100	3	0,226	1332	100	1	0,075	3,011	Algorithm converged.	0,313	28,986	0,151	Algorithm converged.	-0,144	0,445	3,007	Algorithm converged.	0,313	28,869	0,3742		0,333	Algorithm converged.	0,035	3,193
	Ankle fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Cervical vertebral fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Fall	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Gastrointestinal anastomotic stenosis	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Spinal compression fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Tibia fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Upper limb fracture	--	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	1329	100	0	0	1332	100	5	0,375	NE *	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE *	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Dehydration	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Ectopic pregnancy	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998	Algorithm converged.	0,062	15,935	
		Depression	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Mental status changes	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002		Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002		Algorithm converged.	0,063	16,007	1	0,998	Algorithm converged.	0,062	15,935	
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	--	1329	100	1	0,075	1332	100	15	1,126	0,066		Algorithm converged.	0,009	0,501	-1,051	Algorithm converged.	-1,636	-0,465	0,067		Algorithm converged.	0,009	0,505	0,0005		14,966	Algorithm converged.	1,98	113,138

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Acute respiratory failure	--	1329	100	0	0	1332	100	4	0.3	NE	*	Algorithm not converged.	NE	NE	-0.3	Algorithm converged.	-0.594	-0.006	NE	*	Algorithm not converged.	NE	NE	0.1247		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	6	0.45	NE	*	Algorithm not converged.	NE	NE	-0.45	Algorithm converged.	-0.81	-0.091	NE	*	Algorithm not converged.	NE	NE	0.0311		NE	Algorithm not converged.	NE	NE
		Hypoxia	--	1329	100	1	0.075	1332	100	4	0.3	0.25		Algorithm converged.	0.028	2.24	-0.225	Algorithm converged.	-0.554	0.104	0.251		Algorithm converged.	0.028	2.239	0.3745		3.991	Algorithm converged.	0.447	35.66
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Respiratory distress	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Surgical and medical procedures	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vascular disorders	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0.075	NE	*	Algorithm not converged.	NE	NE	-0.075	Algorithm converged.	-0.222	0.072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Sex	Cardiac disorders	--	Male	641	48,232	3	0,468	634	47,598	1	0,158	2,976	Algorithm converged.	0,309	28,691	0,31	Algorithm converged.	-0,302	0,922	2,967	Algorithm converged.	0,309	28,45	0,6244	0,0252	0,337	Algorithm converged.	0,035	3,231
			Female	688	51,768	0	0	698	52,402	3	0,43	NE *	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE *	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Angina pectoris		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		Male	641	48,232	1	0,156	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Gastrointestinal disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,5585	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	5	0,716	0,202		Algorithm converged.	0,024	1,731	-0,571	Algorithm converged.	-1,258	0,116	0,203		Algorithm converged.	0,024	1,732	0,2178		4,928	Algorithm converged.	0,577	42,075	
			Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk						Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE		
		Non-cardiac chest pain	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986	Algorithm converged.	0,062	15,727		
		Pyrexia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Hepatobiliary disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Cholecystitis acute	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Infections and infestations	--	Male	641	48,232	7	1,092	634	47,598	18	2,839	0,378		Algorithm converged.	0,157	0,911	-1,747	Algorithm converged.	-3,27	-0,224	0,385		Algorithm converged.	0,162	0,915	0,0245	0,3952	2,6	Algorithm converged.	1,093	6,181	
			Female	688	51,768	3	0,436	698	52,402	15	2,149	0,199		Algorithm converged.	0,057	0,692	-1,713	Algorithm converged.	-2,896	-0,53	0,203		Algorithm converged.	0,059	0,698	0,0072		4,928	Algorithm converged.	1,433	16,947		
		Bacteraemia	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Breast abscess	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE		
		COVID-19	Male	641	48,232	3	0,468	634	47,598	5	0,789	0,592		Algorithm converged.	0,141	2,486	-0,321	Algorithm converged.	-1,189	0,547	0,593		Algorithm converged.	0,142	2,473	0,5042	0,0481	1,685	Algorithm converged.	0,404	7,021		

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Female	688	51,768	0	0	698	52,402	6	0,86	NE	*	Algorithm not converged.	NE	NE	-0,86	Algorithm converged.	-1,544	-0,175	NE	*	Algorithm not converged.	NE	NE	0,0309		NE	Algorithm not converged.	NE	NE	
		COVID-19 pneumonia	Male	641	48,232	2	0,312	634	47,598	4	0,631	0,493		Algorithm converged.	0,09	2,701	-0,319	Algorithm converged.	-1,071	0,434	0,495		Algorithm converged.	0,091	2,69	0,4497	0,9865	2,022	Algorithm converged.	0,372	11,001	
			Female	688	51,768	1	0,145	698	52,402	2	0,287	0,507		Algorithm converged.	0,046	5,599	-0,141	Algorithm converged.	-0,629	0,347	0,507		Algorithm converged.	0,046	5,581	1		1,971	Algorithm converged.	0,179	21,69	
		Clostridium difficile colitis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Gastroenteritis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Kidney infection	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Lung abscess	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	Male	641	48,232	2	0,312	634	47,598	7	1,104	0,28		Algorithm converged.	0,058	1,355	-0,792	Algorithm converged.	-1,713	0,129	0,283		Algorithm converged.	0,059	1,355	0,1064	0,937	3,539	Algorithm converged.	0,738	16,969	
			Female	688	51,768	1	0,145	698	52,402	4	0,573	0,253		Algorithm converged.	0,028	2,265	-0,428	Algorithm converged.	-1,056	0,2	0,254		Algorithm converged.	0,028	2,263	0,3742		3,943	Algorithm converged.	0,442	35,186	
		Pneumonia viral	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0331	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	3	0,436	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,436	Algorithm converged.	-0,056	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE	Algorithm not converged.	NE	NE
		Ankle fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Fall	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
		Tibia fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Upper limb fracture	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE		
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Metabolism and nutrition disorders	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	4	0,573	NE	*	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,133	-0,013	NE	*	Algorithm not converged.	NE	NE	0,1245		NE		Algorithm not converged.	NE	NE	
		Dehydration	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	
		Hypokalaemia	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Hyponatraemia	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE	
		Musculoskeletal and connective tissue disorders	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	Male	641	48,232	1	0,156	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Gastric cancer	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE		
		Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pregnancy, puerperium and perinatal conditions	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
Ectopic pregnancy	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
Psychiatric disorders	--	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	1	0,143	1,015		Algorithm converged.	0,063	16,253	0,002	Algorithm converged.	-0,398	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986	Algorithm converged.	0,062	15,727
Depression	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
Mental status changes	Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Renal and urinary disorders	--	Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm not converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0943	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm not converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
Nephrolithiasis		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	1	0,145	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm not converged.	-0,139	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE
Renal failure		Male	641	48,232	0	0	634	47,598	1	0,158	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm not converged.	-0,467	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Respiratory, thoracic and mediastinal disorders	--	Male	641	48,232	1	0,156	634	47,598	8	1,262	0,122		Algorithm converged.	0,015	0,98	-1,106	Algorithm converged.	-2,027	-0,185	0,124		Algorithm converged.	0,016	0,986	0,0204	0,2771	8,088	Algorithm converged.	1,015	64,481	
			Female	688	51,768	0	0	698	52,402	7	1,003	NE	*	Algorithm not converged.	NE	NE	-1,003	Algorithm converged.	-1,742	-0,264	NE	*	Algorithm not converged.	NE	NE	0,0154		NE	Algorithm not converged.	NE	NE
Acute respiratory failure		Male	641	48,232	0	0	634	47,598	2	0,315	NE	*	Algorithm not converged.	NE	NE	-0,315	Algorithm converged.	-0,752	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	2	0,287	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,683	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE
Chronic obstructive pulmonary disease		Male	641	48,232	0	0	634	47,598	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Dyspnoea		Male	641	48,232	0	0	634	47,598	3	0,473	NE	*	Algorithm not converged.	NE	NE	-0,473	Algorithm converged.	-1,007	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,768	0	0	698	52,402	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,915	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Hypoxia	Male	641	48,232	1	0,156	634	47,598	4	0,631	0,246	Algorithm converged.	0,027	2,208	-0,475	Algorithm converged.	-1,163	0,213	0,247	Algorithm converged.	0,028	2,206	0,2155	1	4,044	Algorithm converged.	0,453	36,083
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Surgical and medical procedures	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hospitalisation	Male	641	48,232	0	0	634	47,598	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	1	0,143	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,424	0,137	NE	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vascular disorders	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	Male	641	48,232	0	0	634	47,598	1	0,158	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,467	0,151	NE	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,768	0	0	698	52,402	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Age	Cardiac disorders	--	18-64	1168	87,89	2	0,17	1183	88,81	2	0,169	1,013	Algorithm converged.	0,142	7,202	0,002	Algorithm converged.	-0,331	0,335	1,013	Algorithm converged.	0,143	7,178	1	0,5572	0,987	Algorithm converged.	0,139	6,997
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	1	2,857	0,68	Algorithm converged.	0,041	11,25	-0,896	Algorithm converged.	-7,6	5,808	0,686	Algorithm converged.	0,044	10,61	1		1,457	Algorithm converged.	0,094	22,53
	Acute myocardial infarction		18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Angina pectoris		18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		18-64	1168	87,89	0	0	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Coronary artery disease	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Tachycardia	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Nausea	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Vomiting	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	1168	87,89	1	0,09	1183	88,81	3	0,254	0,337		Algorithm converged.	0,035	3,245	-0,168	Algorithm converged.	-0,5	0,164	0,338		Algorithm converged.	0,035	3,241	0,6247		2,962	Algorithm converged.	0,309	28,43	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,85	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE	
		Death	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Fever neonatal	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714		Algorithm converged.	-13,4	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013		Algorithm converged.	0,063	16,21	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1		0,987		Algorithm converged.	0,062	15,77
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pyrexia	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Infections and infestations	--	18-64	1168	87,89	6	0,51	1183	88,81	20	1,691	0,3		Algorithm converged.	0,12	0,75	-1,177		Algorithm converged.	-2,018	-0,34	0,304		Algorithm converged.	0,122	0,754	0,0064	0,95	3,291		Algorithm converged.	1,326	8,166
			65-74	110	8,277	2	1,82	114	8,559	7	6,14	0,283		Algorithm converged.	0,057	1,394	-4,322		Algorithm converged.	-9,387	0,743	0,296		Algorithm converged.	0,063	1,394	0,1714		3,377		Algorithm converged.	0,717	15,9

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>=75	51	3,837	2	3,92	35	2,628	6	17,14	0,197	Algorithm converged.	0,037	1,043	-13,221	Algorithm converged.	-26,8	0,354	0,229	Algorithm converged.	0,049	1,069	0,0579		4,371	Algorithm converged.	0,936	20,42
		Bacteraemia	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Breast abscess	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		COVID-19	18-64	1168	87,89	2	0,17	1183	88,81	4	0,338	0,506	Algorithm converged.	0,092	2,766	-0,167	Algorithm converged.	-0,574	0,24	0,506	Algorithm converged.	0,093	2,76	0,6871	0,2861	1,975	Algorithm converged.	0,362	10,76
			65-74	110	8,277	1	0,91	114	8,559	4	3,509	0,252	Algorithm converged.	0,028	2,294	-2,6	Algorithm converged.	-6,415	1,215	0,259	Algorithm converged.	0,029	2,282	0,3698		3,86	Algorithm converged.	0,438	33,99
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE *	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,85	0,703	NE *	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE
		COVID-19 pneumonia	18-64	1168	87,89	0	0	1183	88,81	2	0,169	NE *	Algorithm not converged.	NE	NE	-0,169	Algorithm converged.	-0,403	0,065	NE *	Algorithm not converged.	NE	NE	0,4998	0,1684	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	2	1,82	114	8,559	1	0,877	2,093	Algorithm converged.	0,187	23,41	0,941	Algorithm converged.	-2,086	3,968	2,073	Algorithm converged.	0,191	22,53	0,6167		0,482	Algorithm converged.	0,044	5,245
			>=75	51	3,837	1	1,96	35	2,628	3	8,571	0,213	Algorithm converged.	0,021	2,141	-6,611	Algorithm converged.	-16,64	3,414	0,229	Algorithm converged.	0,025	2,11	0,2995		4,371	Algorithm converged.	0,474	40,33
		Clostridium difficile colitis	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Gastroenteritis	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Kidney infection	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lung abscess	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	18-64	1168	87,89	2	0,17	1183	88,81	9	0,761	0,224		Algorithm converged.	0,048	1,038	-0,59		Algorithm converged.	-1,139	-0,04	0,225		Algorithm converged.	0,049	1,039	0,0649		4,443	Algorithm converged.	0,962	20,52
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	*	Algorithm not converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	*	Algorithm not converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Sepsis	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Injury, poisoning and procedural complications	--	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013	Algorithm converged.	0,063	16,21	0,001	Algorithm converged.	-0,235	0,237	1,013	Algorithm converged.	0,063	16,17	1	0,4566	0,987	Algorithm converged.	0,062	15,77			
				65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
				>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Ankle fracture	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
				65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
				>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
				65-74	110	8,277	1	0,91	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE	Algorithm not converged.	NE	NE	
				>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE		
				65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
				>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Gastrointestinal anastomotic stenosis	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,96	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Tibia fracture	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	4	3,509	NE	*	Algorithm not converged.	NE	NE	-3,509	Algorithm converged.	-6,886	-0,13	NE	*	Algorithm not converged.	NE	NE	0,1219		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Dehydration	18-64	1168	87.89	0	0	1183	88.81	1	0,085	NE *	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	1168	87.89	0	0	1183	88.81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE *	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	1168	87.89	0	0	1183	88.81	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE *	Algorithm not converged.	NE	NE	-2,632	Algorithm converged.	-5,57	0,307	NE *	Algorithm not converged.	NE	NE	0,2469		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	1168	87.89	1	0,09	1183	88.81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	1168	87.89	1	0,09	1183	88.81	0	0	NE *	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE *	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Gastric cancer	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Pregnancy, puerperium and perinatal conditions	--	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
		Ectopic pregnancy	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
	Psychiatric disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	1	0,085	1,013		Algorithm converged.	0,063	16,21	0,001		Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,17	1	0,987	Algorithm converged.	0,062	15,77	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
		Depression	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Mental status changes	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Nephrolithiasis	18-64	1168	87,89	1	0,09	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	

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ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Respiratory, thoracic and mediastinal disorders	--		18-64	1168	87,89	1	0,09	1183	88,81	10	0,845	0,101	Algorithm converged.	0,013	0,786	-0,76	Algorithm converged.	-1,308	-0,21	0,101	Algorithm converged.	0,013	0,79	0,0116		9,873	Algorithm converged.	1,266	77		
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	5	14,29	NE	*	Algorithm not converged.	NE	NE	-14,286	Algorithm converged.	-25,88	-2,69	NE	*	Algorithm not converged.	NE	NE	0,0093		NE	NE	NE	
Acute respiratory failure			18-64	1168	87,89	0	0	1183	88,81	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	NE	NE	
Chronic obstructive pulmonary disease			18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	NE	NE	
Dyspnoea			18-64	1168	87,89	0	0	1183	88,81	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,85	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	NE	NE	
Hypoxia			18-64	1168	87,89	1	0,09	1183	88,81	4	0,338	0,253	Algorithm converged.	0,028	2,263	-0,253	Algorithm converged.	-0,623	0,118	0,253	Algorithm converged.	0,028	2,262	0,3745		3,949	Algorithm converged.	0,442	35,28		
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

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				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Pulmonary mass	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857		Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Respiratory distress	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Surgical and medical procedures	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hospitalisation	18-64	1168	87,89	0	0	1183	88,81	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877		Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		May-Thurner syndrome	18-64	1168	87,89	0	0	1183	88,81	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,55	205	15,39	3	1,46	0,37				Algorithm converged.	0,038	3,588	-0,917		Algorithm converged.	-2,88	1,043	0,373		0,6255	2,678	Algorithm converged.	0,281	25,52		
			>10^7 copies/mL	590	44,39	2	0,34	561	42,12	1	0,18	1,905				Algorithm converged.	0,172	21,07	0,161		Algorithm converged.	-0,42	0,745	1,902		1	0,526	Algorithm converged.	0,048	5,783		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,55	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,52	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Angina pectoris	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Arrhythmia neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cardiac failure congestive	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Coronary artery disease	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tachycardia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab																	
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk																	
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL													
		Nausea	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Peptic ulcer perforation	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Vomiting	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	General disorders and administration site conditions	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	5	0,89	NE *	Algorithm not converged.	NE	NE	-0,891	Algorithm converged.	-1,67	-0,11	NE *	Algorithm not converged.	NE	NE	0,0273		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Multiple organ dysfunction syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	2	0,36	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
	Hepatobiliary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			<=10^5 copies/mL	370	27,84	0	0	360	27,03	6	1,67	NE	*	Algorithm not converged.	NE	NE	-1,667		Algorithm converged.	-2,99	-0,34	NE	*	Algorithm not converged.	NE	NE	0,0141	0,0218	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	1	0,64	183	13,74	2	1,09	0,58		Algorithm converged.	0,052	6,459	-0,456		Algorithm converged.	-2,41	1,498	0,583		Algorithm converged.	0,053	6,367	1		1,716		Algorithm converged.	0,157	18,74
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	9	4,39	NE	*	Algorithm not converged.	NE	NE	-4,39		Algorithm converged.	-7,2	-1,59	NE	*	Algorithm not converged.	NE	NE	0,004		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	9	1,53	561	42,12	16	2,85	0,528		Algorithm converged.	0,231	1,204	-1,327		Algorithm converged.	-3,02	0,369	0,535		Algorithm converged.	0,238	1,2	0,1229		1,87		Algorithm converged.	0,833	4,196
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Bacteraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		Breast abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE
		COVID-19	<=10^5 copies/mL	370	27,84	0	0	360	27,03	2	0,56	NE *	Algorithm not converged.	NE	NE	-0,556	Algorithm converged.	-1,32	0,212	NE	*	Algorithm not converged.	NE	NE	0,2429	0,2994	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,46	NE *	Algorithm not converged.	NE	NE	-1,463	Algorithm converged.	-3,11	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505	NE	NE	NE	NE	
			>10^7 copies/mL	590	44,39	3	0,51	561	42,12	5	0,89	0,568	Algorithm converged.	0,135	2,389	-0,383	Algorithm converged.	-1,35	0,584	0,571	Algorithm converged.	0,137	2,376	0,4964	1,753	Algorithm converged.	0,421	7,3		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		COVID-19 pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,98	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,32	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	3	0,51	561	42,12	4	0,71	0,712	Algorithm converged.	0,159	3,194	-0,205	Algorithm converged.	-1,11	0,698	0,713		Algorithm converged.	0,16	3,172	0,7194		1,402	Algorithm converged.	0,315	6,237	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	<=10^5 copies/mL	370	27,84	0	0	360	27,03	1	0,28	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,82	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Kidney infection	<=10^5 copies/mL	370	27,84	0	0	360	27,03	1	0,28	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,82	0,266	NE	*	Algorithm not converged.	NE	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Lung abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	1	0,28	NE	*	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,82	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	0,4208	NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	1	0,64	183	13,74	1	0,55	1,167		Algorithm converged.	0,072	18,81	0,09	Algorithm converged.	-1,55	1,73	1,166		Algorithm converged.	0,074	18,48	1		0,858	Algorithm converged.	0,054	13,6	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	3	1,46	NE	*	Algorithm not converged.	NE	NE	-1,463	Algorithm converged.	-3,11	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	2	0,34	561	42,12	6	1,07	0,315		Algorithm converged.	0,063	1,565	-0,731	Algorithm converged.	-1,7	0,241	0,317		Algorithm converged.	0,064	1,564	0,1683		3,155	Algorithm converged.	0,639	15,57	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference			Relative Risk				Relative Risk										
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pneumonia viral	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	<=10^5 copies/mL	370	27,84	0	0	360	27,03	1	0,28	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,82	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	1	0,28	0,973	Algorithm converged.	0,061	15,61	-0,008	Algorithm converged.	-0,77	0,751	0,973		Algorithm converged.	0,061	15,5	1		1,028	Algorithm converged.	0,065	16,37	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,55	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,52	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab															
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk															
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL											
		Ankle fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Cervical vertebral fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Fall	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Gastrointestinal anastomotic stenosis	<=10^5 copies/mL	370	27,84	0	0	360	27,03	1	0,28	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,82	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,55	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	0,546	Algorithm converged.	-0,52	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tibia fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Upper limb fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	3	0,54	NE	*	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,14	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dehydration	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hypokalaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	2	0,36	NE *	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
		Rhabdomyolysis	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
		Gastric cancer	<=10^5 copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE		
	Pregnancy, puerperium and perinatal conditions	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ectopic pregnancy	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm not converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Mental status changes	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm not converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm not converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	1	0,17	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm not converged.	-0,16	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm not converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,03	1	0,28	0,973		Algorithm converged.	0,061	15,61	-0,008	Algorithm converged.	-0,77	0,751	0,973		Algorithm converged.	0,061	15,5	1	0,1957	1,028	Algorithm converged.	0,065	16,37
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	2	0,98	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,32	0,37	NE *	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	11	1,96	NE *	Algorithm not converged.	NE	NE	-1,961	Algorithm converged.	-3,11	-0,81	NE *	Algorithm not converged.	NE	NE	0,0004		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	3	0,54	NE *	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,14	0,069	NE *	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE *	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Dyspnoea	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	1	0,28	NE *	Algorithm not converged.	NE	NE	-0,278	Algorithm converged.	-0,82	0,266	NE *	Algorithm not converged.	NE	NE	0,4932		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	4	0,71	NE	*	Algorithm not converged.	NE	NE	-0,713	Algorithm converged.	-1,41	-0,02	NE	*	Algorithm not converged.	NE	NE	0,0561		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypoxia	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,26	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	1	0,55	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,62	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	2	0,36	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumothorax spontaneous	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,49	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,44	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk					Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,03	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,81	0	0	183	13,74	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,39	0	0	561	42,12	1	0,18	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,53	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RRR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Country	Cardiac disorders	--	USA	1237	93,08	3	0,24	1239	93,02	4	0,32	0,751	Algorithm converged.	0,168	3,361	-0,08	Algorithm converged.	-0,499	0,338	0,751	Algorithm converged.	0,168	3,349	1	1	1,331	Algorithm converged.	0,299	5,935	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Acute myocardial infarction		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Angina pectoris		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Arrhythmia neonatal		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Atrial fibrillation		USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,224	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Cardiac failure congestive		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Coronary artery disease		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
	Tachycardia		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nausea	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	1237	93,08	1	0,08	1239	93,02	4	0,32	0,25		Algorithm converged.	0,028	2,238	-0,242		Algorithm converged.	-0,595	0,111	0,25		Algorithm converged.	0,028	2,237	0,3745	0,3915	3,994	Algorithm converged.	0,447	35,68
			MEX	92	6,922	0	0	93	6,982	2	2,15	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
		Death	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	USA	1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	2	2,15	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,099	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pyrexia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hepatobiliary disorders	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Infections and infestations	USA	1237	93,08	8	0,65	1239	93,02	26	2,1	0,304		Algorithm converged.	0,137	0,673	-1,452		Algorithm converged.	-2,366	-0,54	0,308		Algorithm converged.	0,14	0,678	0,0019	0,9413	3,245	Algorithm converged.	1,475	7,139
			MEX	92	6,922	2	2,17	93	6,982	7	7,53	0,273		Algorithm converged.	0,055	1,351	-5,353		Algorithm converged.	-11,49	0,781	0,289		Algorithm converged.	0,062	1,354	0,169		3,462	Algorithm converged.	0,739	16,23
		Bacteraemia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Breast abscess		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	COVID-19		USA	1237	93,08	1	0,08	1239	93,02	5	0,4	0,2		Algorithm converged.	0,023	1,712	-0,323		Algorithm converged.	-0,71	0,064	0,2		Algorithm converged.	0,023	1,712	0,2182	0,6972	4,992		Algorithm converged.	0,584	42,67
			MEX	92	6,922	2	2,17	93	6,982	6	6,45	0,322		Algorithm converged.	0,063	1,64	-4,278		Algorithm converged.	-10,09	1,537	0,337		Algorithm converged.	0,07	1,626	0,2783		2,968		Algorithm converged.	0,615	14,32
	COVID-19 pneumonia		USA	1237	93,08	3	0,24	1239	93,02	5	0,4	0,6		Algorithm converged.	0,143	2,516	-0,161		Algorithm converged.	-0,608	0,286	0,601		Algorithm converged.	0,144	2,509	0,7261	0,3513	1,664		Algorithm converged.	0,399	6,948
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE	*	Algorithm not converged.	NE	NE	-1,075		Algorithm converged.	-3,171	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
	Clostridium difficile colitis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastroenteritis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Kidney infection		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Lung abscess		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
		Pneumonia	USA	1237	93,08	3	0,24	1239	93,02	11	0,89	0,271	Algorithm converged.	0,076	0,975	-0,645	Algorithm converged.	-1,235	-0,06	0,273	Algorithm converged.	0,076	0,977	0,0567	1	3,661	Algorithm converged.	1,024	13,09
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Pneumonia viral	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Sepsis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	USA	1237	93,08	3	0,24	1239	93,02	1	0,08	3,01	Algorithm converged.	0,313	28,97	0,162	Algorithm converged.	-0,155	0,478	3,005	Algorithm converged.	0,313	28,85	0,3743	1	0,333	Algorithm converged.	0,035	3,195
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ankle fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE *	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Gastrointestinal anastomotic stenosis	USA	MEX	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Spinal compression fracture	USA	MEX	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Tibia fracture	USA	MEX	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Upper limb fracture	USA	MEX	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Metabolism and nutrition disorders	--	USA	1237	93,08	0	0	1239	93,02	5	0,4	NE	*	Algorithm not converged.	NE	NE	-0,404	Algorithm converged.	-0,757	-0,05	NE	*	Algorithm not converged.	NE	NE	0,0622		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Dehydration	USA	MEX	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161	Algorithm converged.	-0,385	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE
Hypokalaemia	USA	MEX	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Hyponatraemia	USA	1237	93,08	0	0	1239	93,02	3	0,24	NE	*	Algorithm not converged.	NE	NE	-0,242	Algorithm converged.	-0,516	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastric cancer	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

			Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Ectopic pregnancy	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Psychiatric disorders	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Depression	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Mental status changes	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,224	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,078	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,08	1	0,08	1239	93,02	14	1,13	0,071	Algorithm converged.	0,009	0,539	-1,049	Algorithm converged.	-1,659	-0,44	0,072	Algorithm converged.	0,009	0,543	0,0009	0,716	13,977	Algorithm converged.	1,841	106,1
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Acute respiratory failure		USA	1237	93,08	0	0	1239	93,02	4	0,32	NE *	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,639	-0,01	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Chronic obstructive pulmonary disease		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Dyspnoea		USA	1237	93,08	0	0	1239	93,02	6	0,48	NE *	Algorithm not converged.	NE	NE	-0,484	Algorithm converged.	-0,871	-0,1	NE *	Algorithm not converged.	NE	NE	0,0311		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Hypoxia		USA	1237	93,08	1	0,08	1239	93,02	4	0,32	0,25	Algorithm converged.	0,028	2,238	-0,242	Algorithm converged.	-0,595	0,111	0,25	Algorithm converged.	0,028	2,237	0,3745	1	3,994	Algorithm converged.	0,447	35,68
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Pneumothorax spontaneous		USA	1237	93,08	0	0	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE *	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,171	1,021	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pulmonary mass		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,239	0,077	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Respiratory distress	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,239	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
All	Cardiac disorders	--	--	1329	100	3	0,226	1332	100	4	0,3	0,751	Algorithm converged.	0,168	3,363	-0,075	Algorithm converged.	-0,464	0,315	0,752	Algorithm converged.	0,169	3,352	1		1,33	Algorithm converged.	0,298	5,932
		Acute myocardial infarction	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Angina pectoris	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Arrhythmia neonatal	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Atrial fibrillation	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935
		Cardiac failure congestive	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Coronary artery disease	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Tachycardia	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Nausea	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Vomiting	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	--	1329	100	1	0,075	1332	100	6	0,45	0,166	Algorithm converged.	0,02	1,384	-0,375	Algorithm converged.	-0,764	0,013	0,167	Algorithm converged.	0,02	1,386	0,1245		5,986	Algorithm converged.	0,722	49,657
		Death	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Fever neonatal	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	--	1329	100	0	0	1332	100	2	0,15	NE *	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE *	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935

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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Pyrexia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Cholecystitis acute	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Infections and infestations	--	--	1329	100	5	0,376	1332	100	16	1,201	0,311		Algorithm converged.	0,113	0,85	-0,825	Algorithm converged.	-1,496	-0,154	0,313		Algorithm converged.	0,115	0,852	0,026		3,193	Algorithm converged.	1,173	8,69
		Bacteraemia	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Breast abscess	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Clostridium difficile colitis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastroenteritis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Kidney infection	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Lung abscess	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pneumonia	--	1329	100	3	0,226	1332	100	11	0,826	0,272		Algorithm converged.	0,076	0,976	-0,6	Algorithm converged.	-1,149	-0,051	0,273		Algorithm converged.	0,076	0,978	0,0567		3,658	Algorithm converged.	1,023	13,084
		Pneumonia viral	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Sepsis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	--	1329	100	3	0,226	1332	100	1	0,075	3,011		Algorithm converged.	0,313	28,986	0,151	Algorithm converged.	-0,144	0,445	3,007		Algorithm converged.	0,313	28,869	0,3742		0,333	Algorithm converged.	0,035	3,193
		Ankle fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Fall	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Gastrointestinal anastomotic stenosis	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Tibia fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	--	1329	100	0	0	1332	100	5	0,375	NE	*	Algorithm not converged.	NE	NE	-0,375	Algorithm converged.	-0,704	-0,047	NE	*	Algorithm not converged.	NE	NE	0,0623		NE	Algorithm not converged.	NE	NE
		Dehydration	--	1329	100	0	0	1332	100	2	0,15	NE	*	Algorithm not converged.	NE	NE	-0,15	Algorithm converged.	-0,358	0,058	NE	*	Algorithm not converged.	NE	NE	0,4998		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	--	1329	100	0	0	1332	100	3	0,225	NE	*	Algorithm not converged.	NE	NE	-0,225	Algorithm converged.	-0,48	0,029	NE	*	Algorithm not converged.	NE	NE	0,2497		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Gastric cancer	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Ectopic pregnancy	--	1329	100	1	0,075	1332	100	0	0	NE	*	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE	*	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	
Psychiatric disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935	
	Depression	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Mental status changes	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE	
Renal and urinary disorders	--	--	1329	100	1	0,075	1332	100	1	0,075	1,002	Algorithm converged.	0,063	16,04	0	Algorithm converged.	-0,208	0,208	1,002	Algorithm converged.	0,063	16,007	1		0,998	Algorithm converged.	0,062	15,935	
		Nephrolithiasis	--	1329	100	1	0,075	1332	100	0	0	NE *	Algorithm not converged.	NE	NE	0,075	Algorithm converged.	-0,072	0,223	NE *	Algorithm not converged.	NE	NE	0,4994		NE	Algorithm not converged.	NE	NE
		Renal failure	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	--	--	1329	100	1	0,075	1332	100	15	1,126	0,066	Algorithm converged.	0,009	0,501	-1,051	Algorithm converged.	-1,636	-0,465	0,067	Algorithm converged.	0,009	0,505	0,0005		14,966	Algorithm converged.	1,98	113,138	
		Acute respiratory failure	--	1329	100	0	0	1332	100	4	0,3	NE *	Algorithm not converged.	NE	NE	-0,3	Algorithm converged.	-0,594	-0,006	NE *	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE
		Chronic obstructive pulmonary disease	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Dyspnoea	--	1329	100	0	0	1332	100	6	0,45	NE *	Algorithm not converged.	NE	NE	-0,45	Algorithm converged.	-0,81	-0,091	NE *	Algorithm not converged.	NE	NE	0,0311		NE	Algorithm not converged.	NE	NE
		Hypoxia	--	1329	100	1	0,075	1332	100	4	0,3	0,25	Algorithm converged.	0,028	2,24	-0,225	Algorithm converged.	-0,554	0,104	0,251	Algorithm converged.	0,028	2,239	0,3745		3,991	Algorithm converged.	0,447	35,66
		Pneumothorax spontaneous	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Pulmonary mass	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Respiratory distress	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
Surgical and medical procedures	--	--	1329	100	0	0	1332	100	1	0,075	NE *	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

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Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Hospitalisation	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	--	1329	100	0	0	1332	100	1	0,075	NE	*	Algorithm not converged.	NE	NE	-0,075	Algorithm converged.	-0,222	0,072	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

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Clinical cut-off: 19Aug2021

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Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL
Sex	Cardiac disorders	--	Male	641	48,23	3	0,47	634	47,6	1	0,16	2,976	Algorithm converged.	0,309	28,69	0,31	Algorithm converged.	-0,3	0,922	2,967	Algorithm converged.	0,309	28,45	0,6244	0,0252	0,337	Algorithm converged.	0,035	3,231
			Female	688	51,77	0	0	698	52,4	3	0,43	NE *	Algorithm not converged.	NE	NE	-0,43	Algorithm converged.	-0,92	0,056	NE *	Algorithm not converged.	NE	NE	0,2495		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Angina pectoris		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1	0,0973	NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE *	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE *	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE *	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Gastrointestinal disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Nausea	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Peptic ulcer perforation	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	General disorders and administration site conditions	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,5585	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	5	0,72	0,202	Algorithm converged.	0,024	1,731	-0,571	Algorithm converged.	-1,26	0,116	0,203		Algorithm converged.	0,024	1,732	0,2178		4,928	Algorithm converged.	0,577	42,08	
		Death	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Fever neonatal	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Multiple organ dysfunction syndrome	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	2	0,29	NE *	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,68	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE		
		Non-cardiac chest pain	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	1	0,14	1,015	Algorithm converged.	0,063	16,25	0,002	Algorithm converged.	-0,4	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986	Algorithm converged.	0,062	15,73		
		Pyrexia	Male	641	48,23	0	0	634	47,6	1	0,16	NE *	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE		
			Female	688	51,77	0	0	698	52,4	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
		Hepatobiliary disorders	--	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Cholecystitis acute	Male	641	48,23	0	0	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE *	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		
		Infections and infestations	--	Male	641	48,23	3	0,47	634	47,6	9	1,42	0,327	Algorithm converged.	0,088	1,212	-0,952	Algorithm converged.	-2,01	0,11	0,33		Algorithm converged.	0,09	1,212	0,0892	0,9012	3,033	Algorithm converged.	0,825	11,15	
			Female	688	51,77	2	0,29	698	52,4	7	1	0,288	Algorithm converged.	0,06	1,39	-0,712	Algorithm converged.	-1,55	0,129	0,29		Algorithm converged.	0,06	1,39	0,1784		3,45	Algorithm converged.	0,719	16,55		
		Bacteraemia	Male	641	48,23	1	0,16	634	47,6	0	0	NE *	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Breast abscess	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Clostridium difficile colitis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Gastroenteritis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Kidney infection	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Lung abscess	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Pneumonia	Male	641	48,23	2	0,31	634	47,6	7	1,1	0,28		Algorithm converged.	0,058	1,355	-0,792		Algorithm converged.	-1,71	0,129	0,283		Algorithm converged.	0,059	1,355	0,1064	0,937	3,539		Algorithm converged.	0,738	16,97	
			Female	688	51,77	1	0,15	698	52,4	4	0,57	0,253		Algorithm converged.	0,028	2,265	-0,428		Algorithm converged.	-1,06	0,2	0,254		Algorithm converged.	0,028	2,263	0,3742		3,943		Algorithm converged.	0,442	35,19	
		Pneumonia viral	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Sepsis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Injury, poisoning and procedural complications	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0331	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	3	0,44	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,436		Algorithm converged.	-0,06	0,928	NE	*	Algorithm not converged.	NE	NE	0,122		NE		Algorithm not converged.	NE	NE	
		Ankle fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Cervical vertebral fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Fall	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Gastrointestinal anastomotic stenosis	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Spinal compression fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Tibia fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
		Upper limb fracture	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145	Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE	Algorithm not converged.	NE	NE	
	Metabolism and nutrition disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	4	0,57	NE	*	Algorithm not converged.	NE	NE	-0,573	Algorithm converged.	-1,13	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1245		NE	Algorithm not converged.	NE	NE	
		Dehydration	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	2	0,29	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,68	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
		Hypokalaemia	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Hyponatraemia	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	1	NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	2	0,29	NE	*	Algorithm not converged.	NE	NE	-0,287	Algorithm converged.	-0,68	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE	Algorithm not converged.	NE	NE	
	Musculoskeletal and connective tissue disorders	--	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156	Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Rhabdomyolysis	Male	641	48,23	1	0,16	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	0,156		Algorithm converged.	-0,15	0,462	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Gastric cancer	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Pregnancy, puerperium and perinatal conditions	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Ectopic pregnancy	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE	
		Psychiatric disorders	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	1	0,14	1,015		Algorithm converged.	0,063	16,25	0,002		Algorithm converged.	-0,4	0,402	1,015		Algorithm converged.	0,064	16,19	1		0,986		Algorithm converged.	0,062	15,73	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Depression	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
		Mental status changes	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973	0,0943	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	1	0,15	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	0,145		Algorithm converged.	-0,14	0,43	NE	*	Algorithm not converged.	NE	NE	0,4964		NE		Algorithm not converged.	NE	NE
		Renal failure	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	Male	641	48,23	1	0,16	634	47,6	8	1,26	0,122		Algorithm converged.	0,015	0,98	-1,106		Algorithm converged.	-2,03	-0,19	0,124		Algorithm converged.	0,016	0,986	0,0204	0,2771	8,088		Algorithm converged.	1,015	64,48
			Female	688	51,77	0	0	698	52,4	7	1	NE	*	Algorithm not converged.	NE	NE	-1,003		Algorithm converged.	-1,74	-0,26	NE	*	Algorithm not converged.	NE	NE	0,0154		NE		Algorithm not converged.	NE	NE
		Acute respiratory failure	Male	641	48,23	0	0	634	47,6	2	0,32	NE	*	Algorithm not converged.	NE	NE	-0,315		Algorithm converged.	-0,75	0,121	NE	*	Algorithm not converged.	NE	NE	0,2471	1	NE		Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	2	0,29	NE	*	Algorithm not converged.	NE	NE	-0,287		Algorithm converged.	-0,68	0,11	NE	*	Algorithm not converged.	NE	NE	0,4997		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Chronic obstructive pulmonary disease	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	NE	1	NE		Algorithm not converged.	NE	NE	
		Dyspnoea	Male	641	48,23	0	0	634	47,6	3	0,47	NE	*	Algorithm not converged.	NE	NE	-0,473		Algorithm converged.	-1,01	0,061	NE	*	Algorithm not converged.	NE	NE	0,1227	1	NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	3	0,43	NE	*	Algorithm not converged.	NE	NE	-0,43		Algorithm converged.	-0,92	0,056	NE	*	Algorithm not converged.	NE	NE	0,2495		NE		Algorithm not converged.	NE	NE	
		Hypoxia	Male	641	48,23	1	0,16	634	47,6	4	0,63	0,246		Algorithm converged.	0,027	2,208	-0,475		Algorithm converged.	-1,16	0,213	0,247		Algorithm converged.	0,028	2,206	0,2155	1	4,044		Algorithm converged.	0,453	36,08	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Pneumothorax spontaneous	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Pulmonary mass	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158		Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Respiratory distress	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143		Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Surgical and medical procedures	--	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Hospitalisation	Male	641	48,23	0	0	634	47,6	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Female	688	51,77	0	0	698	52,4	1	0,14	NE	*	Algorithm not converged.	NE	NE	-0,143	Algorithm converged.	-0,42	0,137	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
	Vascular disorders	--	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	Male	641	48,23	0	0	634	47,6	1	0,16	NE	*	Algorithm not converged.	NE	NE	-0,158	Algorithm converged.	-0,47	0,151	NE	*	Algorithm not converged.	NE	NE	0,4973		NE	Algorithm not converged.	NE	NE	
			Female	688	51,77	0	0	698	52,4	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test		Relative Risk		Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Age	Cardiac disorders	--	18-64	1168	87,886	2	0,171	1183	88,814	2	0,169	1,013	Algorithm converged.	0,142	7,202	0,002	Algorithm converged.	-0,331	0,335	1,013	Algorithm converged.	0,143	7,178	1	0,5572	0,987	Algorithm converged.	0,139	6,997		
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm not converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	1	1,961	35	2,628	1	2,857	0,68		Algorithm converged.	0,041	11,248	-0,896	Algorithm converged.	-7,6	5,808	0,686		Algorithm converged.	0,044	10,609	1		1,457	Algorithm converged.	0,094	22,527
	Acute myocardial infarction		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Angina pectoris		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1	NE	Algorithm not converged.	NE	NE	
	Cardiac failure congestive		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Coronary artery disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Tachycardia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastrointestinal disorders	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Nausea	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Vomiting	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test		Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm not converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	18-64	1168	87,886	1	0,086	1183	88,814	3	0,254	0,337		Algorithm converged.	0,035	3,245	-0,168	Algorithm converged.	-0,5	0,164	0,338		Algorithm converged.	0,035	3,241	0,6247		2,962	Algorithm converged.	0,309	28,434
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	Algorithm converged.	-17,846	0,703	NE	*	Algorithm not converged.	NE	NE	0,064		NE	Algorithm not converged.	NE	NE
		Death	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE
		Fever neonatal	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	2	5,714	NE	*	Algorithm not converged.	NE	NE	-5,714	Algorithm converged.	-13,404	1,976	NE	*	Algorithm not converged.	NE	NE	0,1628		NE	Algorithm not converged.	NE	NE
		Non-cardiac chest pain	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
		Pyrexia	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
	Hepatobiliary disorders	--	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Cholecystitis acute	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Infections and infestations	18-64	1168	87,886	4	0,342	1183	88,814	14	1,183	0,287		Algorithm converged.	0,094	0,874	-0,841		Algorithm converged.	-1,542	-0,14	0,289		Algorithm converged.	0,096	0,877	0,0303	0,1806	3,456		Algorithm converged.	1,141	10,467					
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	*	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	*	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
		Bacteraemia	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Breast abscess	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	*	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE	NE				

Test for interaction based on RR (Log-binomial regression).
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 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab																
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk											
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
		Clostridium difficile colitis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Gastroenteritis	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	*	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Kidney infection	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Lung abscess	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	*	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Pneumonia	18-64	1168	87,886	2	0,171	1183	88,814	9	0,761	0,224		Algorithm converged.	0,048	1,038	-0,59		Algorithm converged.	-1,139	-0,041	0,225		Algorithm converged.	0,049	1,039	0,0649		4,443		Algorithm converged.	0,962	20,519					
			65-74	110	8,277	0	0	114	8,559	2	1,754	NE	*	Algorithm not converged.	NE	NE	-1,754	*	Algorithm converged.	-4,164	0,656	NE	*	Algorithm not converged.	NE	NE	0,4979		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	*	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	NE				

Test for interaction based on RRR (Log-binomial regression).
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 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Pneumonia viral	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	NE	NE	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	NE	NE	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1	0,4566	0,987		Algorithm converged.	0,062	15,766	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961	Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
		Ankle fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Cervical vertebral fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	1	0,909	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	0,909	Algorithm converged.	-0,865	2,683	NE	*	Algorithm not converged.	NE	NE	0,4911		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Fall	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk										
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	1	1,961	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	1,961		Algorithm converged.	-1,844	5,766	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
		Tibia fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Upper limb fracture	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086		Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Metabolism and nutrition disorders	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085		Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	4	3,509	NE	*	Algorithm not converged.	NE	NE	-3,509		Algorithm converged.	-6,886	-0,131	NE	*	Algorithm not converged.	NE	NE	0,1219		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab				
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference						Relative Risk				Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		Dehydration	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm not converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hypokalaemia	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm not converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hyponatraemia	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	3	2,632	NE	*	Algorithm not converged.	NE	NE	-2,632	Algorithm not converged.	-5,57	0,307	NE	*	Algorithm not converged.	NE	NE	0,2469		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm not converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm not converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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POPULATION: SAFETY

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Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab							
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--		18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Gastric cancer			18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Pregnancy, puerperium and perinatal conditions	--		18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Ectopic pregnancy			18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	-0,082	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
Psychiatric disorders	--		18-64	1168	87,886	1	0,086	1183	88,814	1	0,085	1,013		Algorithm converged.	0,063	16,212	0,001	Algorithm converged.	-0,235	0,237	1,013		Algorithm converged.	0,063	16,174	1		0,987	Algorithm converged.	0,062	15,766	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk		Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL					
		Depression	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	1		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Mental status changes	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	NE	NE	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Renal and urinary disorders	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	NE	NE	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	NE	NE	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Nephrolithiasis	18-64	1168	87,886	1	0,086	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	0,086	Algorithm converged.	NE	NE	0,253	NE	*	Algorithm not converged.	NE	NE	0,4968		NE		Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
		Renal failure	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	NE	NE	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE		Algorithm not converged.	NE	NE
		Respiratory, thoracic and mediastinal disorders	18-64	1168	87,886	1	0,086	1183	88,814	10	0,845	0,101		Algorithm converged.	0,013	0,786	-0,76	Algorithm converged.	-1,308	-0,212	0,101		Algorithm converged.	0,013	0,79	0,0116		9,873		Algorithm converged.	1,266	77,004	

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STUDY: R10933-10987-COV-2067

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Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk														
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL									
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*
			>=75	51	3,837	0	0	35	2,628	5	14,286	NE	*	Algorithm not converged.	NE	NE	-14,286	*	Algorithm converged.	-25,879	-2,693	NE	*	Algorithm not converged.	NE	NE	NE	0,0093		NE		Algorithm not converged.	NE	NE	NE			
		Acute respiratory failure	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	*	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE	NE			
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	NE	0,407		NE		Algorithm not converged.	NE	NE	NE			
		Chronic obstructive pulmonary disease	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	*	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	NE	0,407		NE		Algorithm not converged.	NE	NE	NE			
		Dyspnoea	18-64	1168	87,886	0	0	1183	88,814	3	0,254	NE	*	Algorithm not converged.	NE	NE	-0,254	*	Algorithm converged.	-0,54	0,033	NE	*	Algorithm not converged.	NE	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE	NE			
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	3	8,571	NE	*	Algorithm not converged.	NE	NE	-8,571	*	Algorithm converged.	-17,846	0,703	NE	*	Algorithm not converged.	NE	NE	NE	0,064		NE		Algorithm not converged.	NE	NE	NE			
		Hypoxia	18-64	1168	87,886	1	0,086	1183	88,814	4	0,338	0,253		Algorithm converged.	0,028	2,263	-0,253		Algorithm converged.	-0,623	0,118	0,253		Algorithm converged.	0,028	2,262	0,3745		3,949		Algorithm converged.	0,442	35,281					
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
		Pneumothorax spontaneous	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE	NE				

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Interaction Test p-value (likelihood ratio)		Relative Risk		Relative Risk							
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Pulmonary mass	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	1	2,857	NE	*	Algorithm not converged.	NE	NE	-2,857	Algorithm converged.	-8,376	2,662	NE	*	Algorithm not converged.	NE	NE	0,407		NE	Algorithm not converged.	NE	NE	
		Respiratory distress	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	18-64	1168	87,886	0	0	1183	88,814	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	1	0,877	NE	*	Algorithm not converged.	NE	NE	-0,877	Algorithm converged.	-2,589	0,835	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk					
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
		May-Thurner syndrome	18-64	1168	87,886	0	0	1183	88,814	1	0,085	NE	*	Algorithm not converged.	NE	NE	-0,085	Algorithm converged.	-0,25	0,081	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE
			65-74	110	8,277	0	0	114	8,559	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>=75	51	3,837	0	0	35	2,628	0	0	NE	*	Algorithm not converged.	NE	NE	NE	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Baseline viral load categories	Cardiac disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	3	1,463	0,37			-0,038	3,588	-0,917		Algorithm converged.	0,038	3,588	0,373		Algorithm converged.	0,039	3,558	0,6255		2,678		Algorithm converged.	0,281	25,52
			>10^7 copies/mL	590	44,394	2	0,339	561	42,117	1	0,178	1,905			0,172	21,065	0,161		Algorithm converged.	0,172	21,065	0,161		Algorithm converged.	0,173	20,914	1		0,526		Algorithm converged.	0,048	5,783
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Acute myocardial infarction	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Angina pectoris	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Arrhythmia neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Atrial fibrillation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cardiac failure congestive	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Coronary artery disease	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Tachycardia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nausea	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk				
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Peptic ulcer perforation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE *	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Vomiting	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	<=10 ⁵ copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	0,27	Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^7 copies/mL	590	44,394	0	0	561	42,117	5	0,891	NE	*	Algorithm not converged.	NE	NE	-0,891	Algorithm converged.	-1,669	-0,114	NE	*	Algorithm not converged.	NE	NE	0,0273		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Death	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fever neonatal	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pyrexia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Hepatobiliary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
		Cholecystitis acute	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Infections and infestations	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	4	1,111	NE	*	Algorithm not converged.	NE	NE	-1,111		Algorithm converged.	-2,194	-0,028	NE	*	Algorithm not converged.	NE	NE	0,0586	0,1237	NE		Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	1	0,637	183	13,739	1	0,546	1,167		Algorithm converged.	0,072	18,806	0,09		Algorithm converged.	-1,549	1,73	1,166		Algorithm converged.	0,074	18,483	1		0,858		Algorithm converged.	0,054	13,604		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	4	1,951	NE	*	Algorithm not converged.	NE	NE	-1,951		Algorithm converged.	-3,845	-0,058	NE	*	Algorithm not converged.	NE	NE	0,1255		NE		Algorithm not converged.	NE	NE		
			>10^7 copies/mL	590	44,394	4	0,678	561	42,117	7	1,248	0,54		Algorithm converged.	0,157	1,856	-0,57		Algorithm converged.	-1,702	0,563	0,543		Algorithm converged.	0,16	1,846	0,3749		1,84		Algorithm converged.	0,542	6,253		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Bacteraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Breast abscess	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm not converged.	NE	NE	0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Clostridium difficile colitis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	NE	NE	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Gastroenteritis	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		
		Kidney infection	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	NE	NE	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab													
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL						
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
		Lung abscess	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178	*	Algorithm not converged.	NE	NE	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE	NE	NE	NE	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Pneumonia	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278	*	Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	0,4208	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	1	0,637	183	13,739	1	0,546	1,167		Algorithm converged.	0,072	18,806	0,09		Algorithm converged.	-1,549	1,73	1,166		Algorithm converged.	0,074	18,483	1		0,858		0,054	13,604			
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	3	1,463	NE	*	Algorithm not converged.	NE	NE	-1,463	*	Algorithm converged.	-3,107	0,18	NE	*	Algorithm not converged.	NE	NE	0,2505	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁷ copies/mL	590	44,394	2	0,339	561	42,117	6	1,07	0,315		Algorithm converged.	0,063	1,565	-0,731		Algorithm converged.	-1,702	0,241	0,317		Algorithm converged.	0,064	1,564	0,1683	3,155		0,639	15,567				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
		Pneumonia viral	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	*	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Sepsis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973		Algorithm converged.	0,061	15,614	-0,008		Algorithm converged.	-0,766	0,751	0,973		Algorithm converged.	0,061	15,496	1		1,028		Algorithm converged.	0,065	16,369
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546		Algorithm converged.	-0,522	1,615	NE	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ankle fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <= 5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cervical vertebral fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169		Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fall	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Spinal compression fracture	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	1	0,546	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	0,546	*	Algorithm not converged.	NE	NE	0,546	*	Algorithm not converged.	NE	NE	0,4716		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tibia fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	NE	NE	0,27	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).

* indicates convergence problem. Result is uninterpretable.

Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.

95% CI for the relative risk use Farrington-Manning method.

If np <=5 in any treatment group, p-value is based on Fisher Exact Test.

Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
	Metabolism and nutrition disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE	*	Algorithm not converged.	NE	NE	-0,535		Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab										
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk					
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357	Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Rhabdomyolysis	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pregnancy, puerperium and perinatal conditions	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ectopic pregnancy	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Psychiatric disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Depression	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np <=5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab												
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Mental status changes	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27	Algorithm not converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	0,169	Algorithm converged.	-0,162	0,501	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE	NE	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	1	0,278	0,973	Algorithm converged.	0,061	15,614	-0,008	Algorithm converged.	-0,766	0,751	0,973	Algorithm converged.	0,061	15,496	1	0,1957	1,028	Algorithm converged.	0,065	16,369		
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE *	Algorithm not converged.	NE	NE	-0,546	Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	2	0,976	NE *	Algorithm not converged.	NE	NE	-0,976	Algorithm converged.	-2,321	0,37	NE	*	Algorithm not converged.	NE	NE	0,5003		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	11	1,961	NE *	Algorithm not converged.	NE	NE	-1,961	Algorithm converged.	-3,108	-0,813	NE	*	Algorithm not converged.	NE	NE	0,0004		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Acute respiratory failure	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE *	Algorithm not converged.	NE	NE	-0,488	Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			>10^7 copies/mL	590	44,394	0	0	561	42,117	3	0,535	NE *	Algorithm not converged.	NE	NE	-0,535	Algorithm converged.	-1,138	0,069	NE	*	Algorithm not converged.	NE	NE	0,1155		NE	Algorithm not converged.	NE	NE	
			Unknown	29	2,182	0	0	23	1,727	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo				Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Chronic obstructive pulmonary disease	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Dyspnoea	<=10^5 copies/mL	370	27,84	0	0	360	27,027	1	0,278	NE	*	Algorithm not converged.	NE	NE	-0,278		Algorithm converged.	-0,821	0,266	NE	*	Algorithm not converged.	NE	NE	0,4932	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	4	0,713	NE	*	Algorithm not converged.	NE	NE	-0,713		Algorithm converged.	-1,409	-0,017	NE	*	Algorithm not converged.	NE	NE	0,0561	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE
		Hypoxia	<=10^5 copies/mL	370	27,84	1	0,27	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	0,27		Algorithm converged.	-0,259	0,799	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	1	0,546	NE	*	Algorithm not converged.	NE	NE	-0,546		Algorithm converged.	-1,615	0,522	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	-1,442	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	2	0,357	NE	*	Algorithm not converged.	NE	NE	-0,357		Algorithm converged.	-0,85	0,137	NE	*	Algorithm not converged.	NE	NE	0,2373	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
		Pneumothorax spontaneous	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pulmonary mass	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	1	0,488	NE	*	Algorithm not converged.	NE	NE	-0,488		Algorithm converged.	NE	NE	0,466	NE	*	Algorithm not converged.	NE	NE	1	NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Respiratory distress	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10^7 copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	NE	NE	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874	NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Surgical and medical procedures	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo										Placebo vs. Casirivimab/Imdevimab											
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk						
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hospitalisation	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Vascular disorders	--	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm not converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		May-Thurner syndrome	<=10 ⁵ copies/mL	370	27,84	0	0	360	27,027	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁵ copies/mL - <=10 ⁶ copies/mL	157	11,813	0	0	183	13,739	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			>10 ⁶ copies/mL - <=10 ⁷ copies/mL	183	13,77	0	0	205	15,39	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			>10 ⁷ copies/mL	590	44,394	0	0	561	42,117	1	0,178	NE	*	Algorithm not converged.	NE	NE	-0,178		Algorithm converged.	-0,527	0,171	NE	*	Algorithm not converged.	NE	NE	0,4874		NE		Algorithm not converged.	NE	NE
			Unknown	29	2,182	0	0	23	1,727	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab			
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
Country	Cardiac disorders	--	USA	1237	93,08	3	0,24	1239	93,02	4	0,32	0,751	Algorithm converged.	0,168	3,361	-0,08	Algorithm converged.	-0,5	0,338	0,751	Algorithm converged.	0,168	3,349	1	1	1,331	Algorithm converged.	0,299	5,935		
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Acute myocardial infarction		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Angina pectoris		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Arrhythmia neonatal		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Atrial fibrillation		USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002	Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002	Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94		
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Cardiac failure congestive		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE *	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Coronary artery disease		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Tachycardia		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastrointestinal disorders	--	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Nausea	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Peptic ulcer perforation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Vomiting	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	General disorders and administration site conditions	--	USA	1237	93,08	1	0,08	1239	93,02	4	0,32	0,25		Algorithm converged.	0,028	2,238	-0,242		Algorithm converged.	-0,6	0,111	0,25		Algorithm converged.	0,028	2,237	0,3745	0,3915	3,994		Algorithm converged.	0,447	35,68
			MEX	92	6,922	0	0	93	6,982	2	2,15	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,1	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Death	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Fever neonatal	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE

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POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo								Placebo vs. Casirivimab/Imdevimab					
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Multiple organ dysfunction syndrome	USA	1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	2	2,15	NE	*	Algorithm not converged.	NE	NE	-2,151		Algorithm converged.	-5,1	0,798	NE	*	Algorithm not converged.	NE	NE	0,4973		NE		Algorithm not converged.	NE	NE
		Non-cardiac chest pain	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pyrexia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hepatobiliary disorders	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Cholecystitis acute	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Infections and infestations	USA	1237	93,08	5	0,4	1239	93,02	16	1,29	0,31		Algorithm converged.	0,113	0,849	-0,887		Algorithm converged.	-1,61	-0,17	0,313		Algorithm converged.	0,115	0,852	0,026	1	3,195		Algorithm converged.	1,174	8,694
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Bacteraemia	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Breast abscess		USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	*	Algorithm not converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Clostridium difficile colitis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm not converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Gastroenteritis		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm not converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Kidney infection		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm not converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Lung abscess		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm not converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pneumonia		USA	1237	93,08	3	0,24	1239	93,02	11	0,89	0,271		Algorithm converged.	0,076	0,975	-0,645		Algorithm converged.	-1,24	-0,06	0,273		Algorithm converged.	0,076	0,977	0,0567	1	3,661		Algorithm converged.	1,024	13,09
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Pneumonia viral		USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	*	Algorithm not converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
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 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Sepsis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Injury, poisoning and procedural complications	--	USA	1237	93,08	3	0,24	1239	93,02	1	0,08	3,01		Algorithm converged.	0,313	28,97	0,162	Algorithm converged.	-0,16	0,478	3,005		Algorithm converged.	0,313	28,85	0,3743	1	0,333	Algorithm converged.	0,035	3,195	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Ankle fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Cervical vertebral fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Fall	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Gastrointestinal anastomotic stenosis	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Spinal compression fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Tibia fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Upper limb fracture	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Metabolism and nutrition disorders	--	USA	1237	93,08	0	0	1239	93,02	5	0,4	NE	*	Algorithm not converged.	NE	NE	-0,404		Algorithm converged.	-0,76	-0,05	NE	*	Algorithm not converged.	NE	NE	0,0622		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Dehydration	USA	1237	93,08	0	0	1239	93,02	2	0,16	NE	*	Algorithm not converged.	NE	NE	-0,161		Algorithm converged.	-0,39	0,062	NE	*	Algorithm not converged.	NE	NE	0,4998		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hypokalaemia	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Hyponatraemia	USA	1237	93,08	0	0	1239	93,02	3	0,24	NE	*	Algorithm not converged.	NE	NE	-0,242		Algorithm converged.	-0,52	0,032	NE	*	Algorithm not converged.	NE	NE	0,2497		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Musculoskeletal and connective tissue disorders	--	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE

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 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab									
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Interaction Test									
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Rhabdomyolysis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Gastric cancer	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081		Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Pregnancy, puerperium and perinatal conditions	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Ectopic pregnancy	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081		Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
		Psychiatric disorders	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0		Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998		Algorithm converged.	0,063	15,94
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE

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STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL			
		Depression	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Mental status changes	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Renal and urinary disorders	--	USA	1237	93,08	1	0,08	1239	93,02	1	0,08	1,002		Algorithm converged.	0,063	16,03	0	Algorithm converged.	-0,22	0,224	1,002		Algorithm converged.	0,063	16	1	1	0,998	Algorithm converged.	0,063	15,94	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Nephrolithiasis	USA	1237	93,08	1	0,08	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	0,081	Algorithm converged.	-0,08	0,239	NE	*	Algorithm not converged.	NE	NE	0,4996		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Renal failure	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Respiratory, thoracic and mediastinal disorders	--	USA	1237	93,08	1	0,08	1239	93,02	14	1,13	0,071		Algorithm converged.	0,009	0,539	-1,049	Algorithm converged.	-1,66	-0,44	0,072		Algorithm converged.	0,009	0,543	0,0009	0,716	13,977	Algorithm converged.	1,841	106,1	
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,17	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
		Acute respiratory failure	USA	1237	93,08	0	0	1239	93,02	4	0,32	NE	*	Algorithm not converged.	NE	NE	-0,323	Algorithm converged.	-0,64	-0,01	NE	*	Algorithm not converged.	NE	NE	0,1247		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

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 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo						Casirivimab/Imdevimab vs. Placebo						Placebo vs. Casirivimab/Imdevimab								
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk			Relative Risk								
				n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL				
Chronic obstructive pulmonary disease	USA		1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE
Dyspnoea	USA		1237	93,08	0	0	1239	93,02	6	0,48	NE	*	Algorithm not converged.	NE	NE	-0,484	Algorithm converged.	-0,87	-0,1	NE	*	Algorithm not converged.	NE	NE	0,0311		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE
Hypoxia	USA		1237	93,08	1	0,08	1239	93,02	4	0,32	0,25		Algorithm converged.	0,028	2,238	-0,242	Algorithm converged.	-0,6	0,111	0,25		Algorithm converged.	0,028	2,237	0,3745	1	3,994		Algorithm converged.	0,447	35,68	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE
Pneumothorax spontaneous	USA		1237	93,08	0	0	1239	93,02	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE	NE
			MEX	92	6,922	0	0	93	6,982	1	1,08	NE	*	Algorithm not converged.	NE	NE	-1,075	Algorithm converged.	-3,17	1,021	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE
Pulmonary mass	USA		1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE
Respiratory distress	USA		1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE		Algorithm not converged.	NE
Surgical and medical procedures	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE	*	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE		Algorithm not converged.	NE	NE	

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY

ENDPOINT: Any SAEs (excluding disease related events)

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo				Casirivimab/Imdevimab vs. Placebo								Casirivimab/Imdevimab vs. Placebo					Placebo vs. Casirivimab/Imdevimab						
				Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk					Relative Risk						
Name	SOC	PT	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL	p-value	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% upper CL		
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		Hospitalisation	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
	Vascular disorders	--	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE
		May-Thurner syndrome	USA	1237	93,08	0	0	1239	93,02	1	0,08	NE *	Algorithm not converged.	NE	NE	-0,081	Algorithm converged.	-0,24	0,077	NE	*	Algorithm not converged.	NE	NE	1		NE	Algorithm not converged.	NE	NE	
			MEX	92	6,922	0	0	93	6,982	0	0	NE *	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE	*	Algorithm not converged.	NE	NE	NE		NE	Algorithm not converged.	NE	NE

Test for interaction based on RR (Log-binomial regression).
 * indicates convergence problem. Result is uninterpretable.
 Treatment comparison values is derived on Cochran-Mantel-Haenszel (CMH) method.
 95% CI for the relative risk use Farrington-Manning method.
 If np < =5 in any treatment group, p-value is based on Fisher Exact Test.
 Clinical cut-off: 19Aug2021

POPULATION: SAFETY
ENDPOINT: AEs leading to treatment discontinuation
Model: Unstratified analysis
STUDY: R10933-10987-COV-2067
Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
All	Gastrointestinal disorders	--	--	1329	100	1	0,075	1332	100	0	0
		Nausea	--	1329	100	1	0,075	1332	100	0	0

Clinical cut-off: 19Aug2021

Program: t-ae-soc-descriptive.sas
Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Sex	Gastrointestinal disorders	--	Male	641	48,232	1	0,156	634	47,598	0	0
			Female	688	51,768	0	0	698	52,402	0	0
		Nausea	Male	641	48,232	1	0,156	634	47,598	0	0
			Female	688	51,768	0	0	698	52,402	0	0

Clinical cut-off: 19Aug2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Age	Gastrointestinal disorders	--	18-64	1168	87,886	1	0,086	1183	88,814	0	0
			65-74	110	8,277	0	0	114	8,559	0	0
			>=75	51	3,837	0	0	35	2,628	0	0
		Nausea	18-64	1168	87,886	1	0,086	1183	88,814	0	0
			65-74	110	8,277	0	0	114	8,559	0	0
			>=75	51	3,837	0	0	35	2,628	0	0

Clinical cut-off: 19Aug2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

Name	SOC	PT	Level	Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
				n	%	n	%	n	%	n	%
Baseline viral load categories	Gastrointestinal disorders	--	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0
			Unknown	29	2,182	0	0	23	1,727	0	0
		Nausea	<=10^5 copies/mL	370	27,84	0	0	360	27,027	0	0
			>10^5 copies/mL - <=10^6 copies/mL	157	11,813	0	0	183	13,739	0	0
			>10^6 copies/mL - <=10^7 copies/mL	183	13,77	0	0	205	15,39	0	0
			>10^7 copies/mL	590	44,394	1	0,169	561	42,117	0	0
			Unknown	29	2,182	0	0	23	1,727	0	0

Clinical cut-off: 19Aug2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

POPULATION: SAFETY

ENDPOINT: AEs leading to treatment discontinuation

Model: Unstratified analysis

STUDY: R10933-10987-COV-2067

Template Dichotomous analysis (safety)

				Casirivimab/Imdevimab				Placebo			
				Patients		Patients with Event		Patients		Patients with Event	
Name	SOC	PT	Level	n	%	n	%	n	%	n	%
Country	Gastrointestinal disorders	--	USA	1237	93,078	1	0,081	1239	93,018	0	0
			MEX	92	6,922	0	0	93	6,982	0	0
		Nausea	USA	1237	93,078	1	0,081	1239	93,018	0	0
			MEX	92	6,922	0	0	93	6,982	0	0

Clinical cut-off: 19Aug2021

Program: t-ae-soc-descriptive.sas

Output: t20-1-ae-soc-descriptive-trtdc

Datenschnitt 19.08.2021 (DCO2)

Verträglichkeit

Outcome

POPULATION: SAFETY
 ENDPOINT: AESIs
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Outcome of Adverse Events

Category of Adverse Events	Casirivimab/Imdevimab (N=1329)													Placebo (N=1332)																	
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
AESI: Grade 2 or greater infusion-related reactions through Day 4																															
All	3	3	100	0	0	0	0	0	0	0	0	0	0	0	2	2	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2	3	3	100	0	0	0	0	0	0	0	0	0	0	2	2	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Serious AESI: Grade 2 or greater infusion-related reactions through Day 4																															
All	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AESI: Grade 2 or greater Hypersensitivity reactions through Day 29																															
All	1	1	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2	1	1	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Serious AESI: Grade 2 or greater Hypersensitivity reactions through Day 29																															
All	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Clinical cut-off: 19Aug2021

Program: t-ae-resolved-aeis.sas

Output: t17-ae-resolved-aeis

POPULATION: SAFETY
 ENDPOINT: Adverse Events
 Model: Unstratified analysis
 STUDY: R10933-10987-COV-2067
 Template Outcome of Adverse Events

Category of Adverse Events	Casirivimab/Imdevimab (N=1329)														Placebo (N=1332)																	
	Total	RECOVERED/RESOLVED			RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED			RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Any AEs	208	132	63.462	4	1.923	43	20.673	1	0.481	27	12.981	1	0.481	0	0	277	200	72.202	3	1.083	47	16.968	7	2.527	19	6.859	1	0.361	0	0		
Grade 1	116	68	58.621	1	0.862	31	26.724	0	0	15	12.931	1	0.862	0	0	126	83	65.873	1	0.794	28	22.222	0	0	14	11.111	0	0	0	0		
Grade 2	58	42	72.414	2	3.448	5	8.621	0	0	9	15.517	0	0	0	0	78	68	87.179	0	0	6	7.692	0	0	3	3.846	1	1.282	0	0		
Grade 3	31	21	67.742	1	3.226	7	22.581	0	0	2	6.452	0	0	0	0	57	46	80.702	2	3.509	7	12.281	0	0	2	3.509	0	0	0	0		
Grade 4	2	1	50	0	0	0	0	0	0	1	50	0	0	0	0	9	3	33.333	0	0	6	66.667	0	0	0	0	0	0	0	0		
Grade 5	1	0	0	0	0	0	0	1	100	0	0	0	0	0	0	7	0	0	0	0	0	0	7	100	0	0	0	0	0	0		
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Any SAEs	30	22	73.333	0	0	5	16.667	1	3.333	2	6.667	0	0	0	0	78	56	71.795	2	2.564	12	15.385	7	8.974	1	1.282	0	0	0	0		
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	8	100	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 2	6	6	100	0	0	0	0	0	0	0	0	0	0	0	8	7	87.5	0	0	1	12.5	0	0	0	0	0	0	0	0	0		
Grade 3	21	15	71.429	0	0	5	23.81	0	0	1	4.762	0	0	0	0	46	38	82.609	2	4.348	5	10.87	0	0	1	2.174	0	0	0	0		
Grade 4	2	1	50	0	0	0	0	0	0	1	50	0	0	0	0	9	3	33.333	0	0	6	66.667	0	0	0	0	0	0	0	0		
Grade 5	1	0	0	0	0	0	0	1	100	0	0	0	0	0	0	7	0	0	0	0	0	0	7	100	0	0	0	0	0	0		
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Any AESTs	4	4	100	0	0	0	0	0	0	0	0	0	0	0	0	2	2	100	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 2	4	4	100	0	0	0	0	0	0	0	0	0	0	0	2	2	100	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

Clinical cut-off: 19Aug2021

Program: t-ae-resolved-general.sas
 Output: t16-ae-resolved-general

Datenschnitt 19.08.2021 (DCO2)

Verträglichkeit

Ergänzende Dokumente

Clinical cut-off: 19Aug2021

**Table 2.1: Duration of Follow-up by domain and arm
Safety Analysis Set**

Study: R10933-10987-COV-2067

	Treatment	
	Placebo (N = 1332)	Casirivimab/Imdevimab (N = 1329)
Efficacy Follow-up (Days)		
Median	29.0	29.0
Safety 1 Follow-up (Days)		
Median	29.0	29.0
Safety 2 Follow-up (Days)		
Median	169.0	169.0