Anhang 4-G: Ergänzende Angaben

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Anhang 4-G1: Ergänzende Angaben zur Darstellung der Unerwünschten Ereignisse in den Studien SUPERNOVA und NOVELLA

Anhang 4-G1.1: Definition der Folgekomplikationen in den Studien SUPERNOVA und NOVELLA

Tabelle 4-G1.1-1: Definition der Folgekomplikationen in den Studien SUPERNOVA und NOVELLA

Definition der Folgekomplikationen in den Studien SUPERNOVA und NOVELLA	
Coded Term PT	**SOC**
Lymphadenopathy	Blood and lymphatic system disorders
Arrhythmia	Cardiac disorders
Atrial fibrillation	Cardiac disorders
Tachycardia	Cardiac disorders
Ear pain	Ear and labyrinth disorders
Diarrhoea	Gastrointestinal disorders
Nausea	Gastrointestinal disorders
Chest discomfort	General disorders and administration site conditions
Pain	General disorders and administration site conditions
Atypical pneumonia	Infections and infestations
Bronchitis	Infections and infestations
COVID-19	Infections and infestations
COVID-19 pneumonia	Infections and infestations
Lower respiratory tract infection	Infections and infestations
Myringitis	Infections and infestations
Nasal herpes	Infections and infestations
Pharyngitis	Infections and infestations
Pneumonia	Infections and infestations
Pneumonia bacterial	Infections and infestations
Post-acute COVID-19 syndrome	Infections and infestations
Sepsis	Infections and infestations
Sinusitis	Infections and infestations
Superinfection bacterial	Infections and infestations
Suspected COVID-19	Infections and infestations
Hypoglycaemia	Metabolism and nutrition disorders
Hypokalaemia	Metabolism and nutrition disorders
Arthralgia	Musculoskeletal and connective tissue disorders
Rhabdomyolysis	Musculoskeletal and connective tissue disorders
Disturbance in attention	Nervous system disorders
Dizziness	Nervous system disorders
Headache	Nervous system disorders
Syncope	Nervous system disorders
Dysuria	Renal and urinary disorders
Asthma	Respiratory, thoracic and mediastinal disorders
Bronchiectasis	Respiratory, thoracic and mediastinal disorders

Haemoptysis	Respiratory, thoracic and mediastinal disorders
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders
Hypertension	Vascular disorders
Hypotension	Vascular disorders

Anhang 4-G1.2: Operationalisierung der UESI in den Studien SUPERNOVA und NOVELLA

Tabelle 4-G1.2-1: Operationalisierung der UESI

Unerwünschte Ereignisse von speziellem Interesse	
UESI	**Suche MedDRA PT und weitere Kriterien**
Anaphylaxie und andere schwere Überempfindlichkeitsreaktionen	PT Search: • Narrow search SMQ – Hypersensitivity • Broad Search SMQ – Angioedema • PT – Idiopathic angioedema • PT – Idiopathic urticaria AND Serious Adverse Event and/or ≥ Grade 3 Severity AND Within 30 days of any IMP administration
Immunkomplexerkrankungen	PT Typ-III-Allergie (Type III immune complex mediated reaction)
Kardiovaskuläre und thrombotische Ereignisse	PT Search: • Narrow search SMQ Myocardial infarction • Broad and narrow search SMQ Cardiac failure • Narrow search SMQ Embolic and thrombotic events • Narrow search SMQ Ischaemic central nervous system vascular conditions • Narrow search SMQ haemorrhagic central nervous system vascular conditions AND Independent CV Adjudication Committee assessment

Anhang 4-G2: Ergebnisse der Sensitivitätsanalyse zur Symptomspezifischen Wirksamkeit nach Treatment Policy Strategie in der Sudie SUPERNOVA

Anhang 4-G2.1: Anteil an Patient:innen mit symptomatischer COVID-19

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	28 (5.1)	50 (9.5)
Number of censored subjects, n (%)	520 (94.9)	475 (90.5)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.52 (0.33, 0.82)	
p-value	0.0055	
Relative Risk (95% CI) [3]	0.57 (0.36, 0.89)	
p-value	0.0127	
Odds Ratio (95% CI) [3]	0.54 (0.33, 0.87)	
p-value	0.0115	
Risk Difference (95% CI) [3]	-4.41 (-7.52, -1.29)	
p-value	0.0056	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.52 (0.33, 0.83)	
p-value	0.0060	
Relative Risk (95% CI) [3]	0.54 (0.34, 0.84)	
p-value	0.0063	
Odds Ratio (95% CI) [3]	0.51 (0.32, 0.83)	
p-value	0.0061	
Risk Difference (95% CI) [3]	-4.41 (-7.53, -1.30)	
p-value	0.0055	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.7803
< 65	19/ 360 (5.3)	36/ 352 (10.2)	0.50 (0.29, 0.87)	0.0150	
>= 65	9/ 188 (4.8)	14/ 173 (8.1)	0.58 (0.25, 1.33)	0.1998	
Sex					0.6902
Male	11/ 249 (4.4)	25/ 274 (9.1)	0.47 (0.23, 0.95)	0.0346	
Female	17/ 299 (5.7)	25/ 251 (10.0)	0.56 (0.31, 1.04)	0.0671	
Region					0.4068
US	15/ 323 (4.6)	18/ 272 (6.6)	0.70 (0.35, 1.38)	0.3017	
Europe	11/ 158 (7.0)	22/ 173 (12.7)	0.52 (0.26, 1.08)	0.0793	
Other	2/ 67 (3.0)	10/ 80 (12.5)	0.23 (0.05, 1.02)	0.0537	
COVID-19 vaccination status within six months prior to randomization					0.8948
Yes	5/ 74 (6.8)	9/ 78 (11.5)	0.56 (0.19, 1.67)	0.2994	
No	23/ 474 (4.9)	41/ 447 (9.2)	0.52 (0.31, 0.86)	0.0113	
Prior SARS-CoV-2 infection within six months prior to randomization					1.0000
Yes **	0/ 24 (0.0)	1/ 27 (3.7)	1.11 (0.00, 43.20)	0.5255	
No *	28/ 524 (5.3)	49/ 498 (9.8)	0.53 (0.32, 0.86)	0.0086	
AZD7442 use within 12 months prior to randomization					0.5417
Yes	3/ 100 (3.0)	8/ 98 (8.2)	0.36 (0.09, 1.34)	0.1271	
No	25/ 448 (5.6)	42/ 427 (9.8)	0.55 (0.34, 0.91)	0.0191	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.9826
Yes	5/ 94 (5.3)	10/ 101 (9.9)	0.52 (0.18, 1.51)	0.2290	
No	23/ 454 (5.1)	40/ 424 (9.4)	0.52 (0.31, 0.88)	0.0136	
Solid organ or stem cell transplants					0.8114
Yes	14/ 268 (5.2)	24/ 263 (9.1)	0.55 (0.29, 1.07)	0.0795	
No	14/ 280 (5.0)	26/ 262 (9.9)	0.50 (0.26, 0.94)	0.0330	
Solid tumor cancer and on active treatment					0.6267
Yes **	1/ 18 (5.6)	0/ 20 (0.0)	1.25 (0.03, I)	0.4444	
No *	27/ 530 (5.1)	50/ 505 (9.9)	0.50 (0.30, 0.81)	0.0042	
Taking immunosuppressive medicines					0.9998
Yes	26/ 491 (5.3)	46/ 464 (9.9)	0.52 (0.32, 0.84)	0.0077	
No	2/ 57 (3.5)	4/ 61 (6.6)	0.52 (0.10, 2.83)	0.4497	
Electrocardiogram (ECG) interpretation					0.0093
Normal	16/ 328 (4.9)	41/ 332 (12.3)	0.38 (0.21, 0.67)	0.0010	
Abnormal	12/ 184 (6.5)	7/ 171 (4.1)	1.62 (0.64, 4.11)	0.3098	
Body Mass Index					0.9772
<30 kg/m2	18/ 348 (5.2)	34/ 368 (9.2)	0.55 (0.31, 0.96)	0.0368	
>=30 kg/m2	10/ 198 (5.1)	14/ 151 (9.3)	0.54 (0.24, 1.21)	0.1337	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.6287
Yes	7/ 100 (7.0)	10/ 94 (10.6)	0.64 (0.25, 1.67)	0.3657	
No	21/ 448 (4.7)	40/ 431 (9.3)	0.49 (0.29, 0.83)	0.0085	
Moderate or severe secondary Immunodeficiency					0.6754
Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.94 (0.06, 15.46)	0.9673	
No	27/ 525 (5.1)	49/ 505 (9.7)	0.51 (0.32, 0.82)	0.0055	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 180) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	49 (8.9)	70 (13.3)
Number of censored subjects, n (%)	499 (91.1)	455 (86.7)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.64 (0.44, 0.92)	
p-value	0.0170	
Relative Risk (95% CI) [3]	0.68 (0.48, 0.97)	
p-value	0.0307	
Odds Ratio (95% CI) [3]	0.65 (0.44, 0.96)	
p-value	0.0291	
Risk Difference (95% CI) [3]	-4.40 (-8.16, -0.64)	
p-value	0.0219	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.64 (0.44, 0.92)	
p-value	0.0173	
Relative Risk (95% CI) [3]	0.67 (0.48, 0.95)	
p-value	0.0232	
Odds Ratio (95% CI) [3]	0.64 (0.43, 0.94)	
p-value	0.0228	
Risk Difference (95% CI) [3]	-4.39 (-8.16, -0.63)	
p-value	0.0222	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.7267
< 65	36/ 360 (10.0)	50/ 352 (14.2)	0.67 (0.44, 1.03)	0.0669	
>= 65	13/ 188 (6.9)	20/ 173 (11.6)	0.58 (0.29, 1.16)	0.1250	
Sex					0.6737
Male	21/ 249 (8.4)	37/ 274 (13.5)	0.59 (0.34, 1.01)	0.0523	
Female	28/ 299 (9.4)	33/ 251 (13.1)	0.69 (0.42, 1.15)	0.1508	
Region					0.4737
US	28/ 323 (8.7)	29/ 272 (10.7)	0.80 (0.48, 1.35)	0.4018	
Europe	17/ 158 (10.8)	30/ 173 (17.3)	0.58 (0.32, 1.06)	0.0753	
Other	4/ 67 (6.0)	11/ 80 (13.8)	0.39 (0.12, 1.24)	0.1102	
COVID-19 vaccination status within six months prior to randomization					0.5503
Yes	6/ 74 (8.1)	12/ 78 (15.4)	0.49 (0.18, 1.31)	0.1522	
No	43/ 474 (9.1)	58/ 447 (13.0)	0.67 (0.45, 1.00)	0.0488	
Prior SARS-CoV-2 infection within six months prior to randomization					0.4025
Yes	1/ 24 (4.2)	4/ 27 (14.8)	0.26 (0.03, 2.27)	0.2218	
No	48/ 524 (9.2)	66/ 498 (13.3)	0.66 (0.46, 0.96)	0.0302	
AZD7442 use within 12 months prior to randomization					0.7595
Yes	8/ 100 (8.0)	13/ 98 (13.3)	0.57 (0.24, 1.36)	0.2028	
No	41/ 448 (9.2)	57/ 427 (13.3)	0.66 (0.44, 0.98)	0.0419	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.3392
Yes	7/ 94 (7.4)	16/ 101 (15.8)	0.43 (0.18, 1.06)	0.0663	
No	42/ 454 (9.3)	54/ 424 (12.7)	0.70 (0.47, 1.05)	0.0832	
Solid organ or stem cell transplants					0.6612
Yes	24/ 268 (9.0)	32/ 263 (12.2)	0.70 (0.41, 1.19)	0.1852	
No	25/ 280 (8.9)	38/ 262 (14.5)	0.59 (0.36, 0.98)	0.0426	
Solid tumor cancer and on active treatment					0.7071
Yes **	1/ 18 (5.6)	0/ 20 (0.0)	1.26 (0.03, I)	0.4431	
No *	48/ 530 (9.1)	70/ 505 (13.9)	0.62 (0.42, 0.91)	0.0131	
Taking immunosuppressive medicines					0.7639
Yes	46/ 491 (9.4)	64/ 464 (13.8)	0.65 (0.44, 0.95)	0.0250	
No	3/ 57 (5.3)	6/ 61 (9.8)	0.52 (0.13, 2.09)	0.3558	
Electrocardiogram (ECG) interpretation					0.2213
Normal	31/ 328 (9.5)	51/ 332 (15.4)	0.57 (0.37, 0.90)	0.0147	
Abnormal	17/ 184 (9.2)	17/ 171 (9.9)	0.95 (0.48, 1.86)	0.8751	
Body Mass Index					0.2637
<30 kg/m2	29/ 348 (8.3)	52/ 368 (14.1)	0.56 (0.35, 0.88)	0.0124	
>=30 kg/m2	19/ 198 (9.6)	16/ 151 (10.6)	0.89 (0.45, 1.73)	0.7258	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.5572
Yes	8/ 100 (8.0)	14/ 94 (14.9)	0.51 (0.21, 1.21)	0.1267	
No	41/ 448 (9.2)	56/ 431 (13.0)	0.67 (0.45, 1.01)	0.0566	
Moderate or severe secondary Immunodeficiency					0.7732
Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.96 (0.06, 16.17)	0.9801	
No	48/ 525 (9.1)	69/ 505 (13.7)	0.64 (0.44, 0.92)	0.0161	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G2.2: Anteil an Patient:innen mit symptomatischer COVID-19 (SARS-CoV-2-Varianten ohne F456L-Mutation)

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	7 (1.3)	23 (4.4)
Number of censored subjects, n (%)	541 (98.7)	502 (95.6)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.29 (0.12, 0.66)	
p-value	0.0036	
Relative Risk (95% CI) [3]	0.31 (0.14, 0.70)	
p-value	0.0048	
Odds Ratio (95% CI) [3]	0.30 (0.13, 0.69)	
p-value	0.0045	
Risk Difference (95% CI) [3]	-3.12 (-5.11, -1.13)	
p-value	0.0021	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.29 (0.12, 0.67)	
p-value	0.0038	
Relative Risk (95% CI) [3]	0.29 (0.13, 0.67)	
p-value	0.0039	
Odds Ratio (95% CI) [3]	0.28 (0.12, 0.66)	
p-value	0.0037	
Risk Difference (95% CI) [3]	-3.10 (-5.09, -1.12)	
p-value	0.0022	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.9370
< 65	5/ 360 (1.4)	17/ 352 (4.8)	0.28 (0.10, 0.76)	0.0127	
>= 65	2/ 188 (1.1)	6/ 173 (3.5)	0.30 (0.06, 1.51)	0.1447	
Sex					0.4545
Male	4/ 249 (1.6)	11/ 274 (4.0)	0.40 (0.13, 1.24)	0.1114	
Female	3/ 299 (1.0)	12/ 251 (4.8)	0.21 (0.06, 0.73)	0.0142	
Region					0.6830
US	2/ 323 (0.6)	3/ 272 (1.1)	0.56 (0.09, 3.36)	0.5275	
Europe	4/ 158 (2.5)	13/ 173 (7.5)	0.33 (0.11, 1.00)	0.0494	
Other	1/ 67 (1.5)	7/ 80 (8.8)	0.17 (0.02, 1.33)	0.0902	
COVID-19 vaccination status within six months prior to randomization					0.8628
Yes	1/ 74 (1.4)	3/ 78 (3.8)	0.35 (0.04, 3.30)	0.3559	
No	6/ 474 (1.3)	20/ 447 (4.5)	0.28 (0.11, 0.69)	0.0060	
Prior SARS-CoV-2 infection within six months prior to randomization					1.0000
Yes **	0/ 24 (0.0)	1/ 27 (3.7)	1.11 (0.00, 43.20)	0.5255	
No *	7/ 524 (1.3)	22/ 498 (4.4)	0.30 (0.11, 0.72)	0.0048	
AZD7442 use within 12 months prior to randomization					0.8676
Yes	1/ 100 (1.0)	4/ 98 (4.1)	0.24 (0.03, 2.17)	0.2045	
No	6/ 448 (1.3)	19/ 427 (4.4)	0.30 (0.12, 0.74)	0.0092	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.9369
Yes	1/ 94 (1.1)	4/ 101 (4.0)	0.26 (0.03, 2.35)	0.2327	
No	6/ 454 (1.3)	19/ 424 (4.5)	0.29 (0.12, 0.73)	0.0082	
Solid organ or stem cell transplants					0.7002
Yes	3/ 268 (1.1)	12/ 263 (4.6)	0.24 (0.07, 0.85)	0.0272	
No	4/ 280 (1.4)	11/ 262 (4.2)	0.34 (0.11, 1.05)	0.0612	
Solid tumor cancer and on active treatment					NE
Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
No *	7/ 530 (1.3)	23/ 505 (4.6)	0.28 (0.10, 0.69)	0.0030	
Taking immunosuppressive medicines					0.3330
Yes	6/ 491 (1.2)	22/ 464 (4.7)	0.25 (0.10, 0.62)	0.0028	
No	1/ 57 (1.8)	1/ 61 (1.6)	1.06 (0.07, 16.87)	0.9644	
Electrocardiogram (ECG) interpretation					0.1113
Normal	3/ 328 (0.9)	17/ 332 (5.1)	0.17 (0.05, 0.59)	0.0052	
Abnormal	4/ 184 (2.2)	5/ 171 (2.9)	0.75 (0.20, 2.78)	0.6661	
Body Mass Index					0.5171
<30 kg/m2	5/ 348 (1.4)	15/ 368 (4.1)	0.35 (0.13, 0.95)	0.0397	
>=30 kg/m2	2/ 198 (1.0)	8/ 151 (5.3)	0.19 (0.04, 0.89)	0.0345	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.5282
Yes	2/ 100 (2.0)	4/ 94 (4.3)	0.47 (0.09, 2.51)	0.3738	
No	5/ 448 (1.1)	19/ 431 (4.4)	0.25 (0.09, 0.67)	0.0056	
Moderate or severe secondary Immunodeficiency					NE
Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
No *	7/ 525 (1.3)	23/ 505 (4.6)	0.29 (0.10, 0.69)	0.0032	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	25 (4.6)	35 (6.7)
Number of censored subjects, n (%)	523 (95.4)	490 (93.3)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.67 (0.40, 1.11)	
p-value	0.1189	
Relative Risk (95% CI) [3]	0.73 (0.44, 1.20)	
p-value	0.2131	
Odds Ratio (95% CI) [3]	0.71 (0.42, 1.21)	
p-value	0.2099	
Risk Difference (95% CI) [3]	-2.07 (-4.82, 0.69)	
p-value	0.1418	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.66 (0.40, 1.11)	
p-value	0.1178	
Relative Risk (95% CI) [3]	0.68 (0.42, 1.13)	
p-value	0.1363	
Odds Ratio (95% CI) [3]	0.67 (0.39, 1.13)	
p-value	0.1358	
Risk Difference (95% CI) [3]	-2.10 (-4.86, 0.65)	
p-value	0.1347	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.8915
< 65	18/ 360 (5.0)	25/ 352 (7.1)	0.68 (0.37, 1.25)	0.2136	
>= 65	7/ 188 (3.7)	10/ 173 (5.8)	0.63 (0.24, 1.65)	0.3469	
Sex					0.9488
Male	11/ 249 (4.4)	18/ 274 (6.6)	0.65 (0.31, 1.38)	0.2612	
Female	14/ 299 (4.7)	17/ 251 (6.8)	0.67 (0.33, 1.36)	0.2730	
Region					0.1415
US	14/ 323 (4.3)	9/ 272 (3.3)	1.31 (0.57, 3.01)	0.5232	
Europe	9/ 158 (5.7)	19/ 173 (11.0)	0.49 (0.22, 1.09)	0.0790	
Other	2/ 67 (3.0)	7/ 80 (8.8)	0.32 (0.07, 1.54)	0.1546	
COVID-19 vaccination status within six months prior to randomization					0.6575
Yes	3/ 74 (4.1)	6/ 78 (7.7)	0.50 (0.13, 1.98)	0.3221	
No	22/ 474 (4.6)	29/ 447 (6.5)	0.70 (0.40, 1.21)	0.2021	
Prior SARS-CoV-2 infection within six months prior to randomization					1.0000
Yes **	0/ 24 (0.0)	4/ 27 (14.8)	0.19 (0.00, 1.53)	0.0641	
No *	25/ 524 (4.8)	31/ 498 (6.2)	0.75 (0.42, 1.31)	0.3409	
AZD7442 use within 12 months prior to randomization					0.2911
Yes	3/ 100 (3.0)	8/ 98 (8.2)	0.35 (0.09, 1.31)	0.1194	
No	22/ 448 (4.9)	27/ 427 (6.3)	0.76 (0.43, 1.33)	0.3334	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.1714
Yes	3/ 94 (3.2)	10/ 101 (9.9)	0.30 (0.08, 1.09)	0.0672	
No	22/ 454 (4.8)	25/ 424 (5.9)	0.80 (0.45, 1.43)	0.4565	
Solid organ or stem cell transplants					0.7596
Yes	11/ 268 (4.1)	17/ 263 (6.5)	0.61 (0.29, 1.30)	0.1992	
No	14/ 280 (5.0)	18/ 262 (6.9)	0.72 (0.36, 1.43)	0.3457	
Solid tumor cancer and on active treatment					NE
Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
No *	25/ 530 (4.7)	35/ 505 (6.9)	0.66 (0.38, 1.13)	0.1406	
Taking immunosuppressive medicines					0.6184
Yes	23/ 491 (4.7)	33/ 464 (7.1)	0.64 (0.38, 1.08)	0.0964	
No	2/ 57 (3.5)	2/ 61 (3.3)	1.07 (0.15, 7.55)	0.9479	
Electrocardiogram (ECG) interpretation					0.7347
Normal	15/ 328 (4.6)	23/ 332 (6.9)	0.63 (0.33, 1.21)	0.1665	
Abnormal	9/ 184 (4.9)	11/ 171 (6.4)	0.76 (0.32, 1.84)	0.5480	
Body Mass Index					0.5079
<30 kg/m2	14/ 348 (4.0)	25/ 368 (6.8)	0.57 (0.30, 1.10)	0.0942	
>=30 kg/m2	11/ 198 (5.6)	10/ 151 (6.6)	0.82 (0.35, 1.93)	0.6555	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.4711
Yes	4/ 100 (4.0)	8/ 94 (8.5)	0.45 (0.14, 1.48)	0.1887	
No	21/ 448 (4.7)	27/ 431 (6.3)	0.73 (0.41, 1.29)	0.2775	
Moderate or severe secondary Immunodeficiency					NE
Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
No *	25/ 525 (4.8)	35/ 505 (6.9)	0.66 (0.38, 1.14)	0.1478	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G2.3: Anteil an Patient:innen mit schwerer COVID-19

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 90) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Number of censored subjects, n (%)	547 (99.8)	524 (99.8)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.99 (0.07, 14.86)	
p-value	0.9943	
Relative Risk (95% CI) [3]	0.95 (0.10, 9.05)	
p-value	0.9645	
Odds Ratio (95% CI) [3]	0.95 (0.10, 9.26)	
p-value	0.9680	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9745	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.96 (0.06, 15.30)	
p-value	0.9759	
Relative Risk (95% CI) [3]	0.96 (0.06, 15.28)	
p-value	0.9758	
Odds Ratio (95% CI) [3]	0.96 (0.06, 15.35)	
p-value	0.9758	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9758	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	1/ 188 (0.5)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	1/ 299 (0.3)	0/ 251 (0.0)			
Region					
US	1/ 323 (0.3)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	1/ 78 (1.3)			
No	1/ 474 (0.2)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	1/ 524 (0.2)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	1/ 448 (0.2)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	1/ 101 (1.0)			
No	1/ 454 (0.2)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	1/ 280 (0.4)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	1/ 530 (0.2)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	1/ 491 (0.2)	0/ 464 (0.0)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	1/ 198 (0.5)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	1/ 448 (0.2)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	1/ 505 (0.2)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 180) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Number of censored subjects, n (%)	547 (99.8)	524 (99.8)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.97 (0.06, 14.86)	
p-value	0.9854	
Relative Risk (95% CI) [3]	0.95 (0.10, 9.05)	
p-value	0.9645	
Odds Ratio (95% CI) [3]	0.95 (0.10, 9.26)	
p-value	0.9680	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9745	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.95 (0.06, 15.20)	
p-value	0.9711	
Relative Risk (95% CI) [3]	0.96 (0.06, 15.28)	
p-value	0.9758	
Odds Ratio (95% CI) [3]	0.96 (0.06, 15.35)	
p-value	0.9758	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9758	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	1/ 188 (0.5)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	1/ 299 (0.3)	0/ 251 (0.0)			
Region					
US	1/ 323 (0.3)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	1/ 78 (1.3)			
No	1/ 474 (0.2)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	1/ 524 (0.2)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	1/ 448 (0.2)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	1/ 101 (1.0)			
No	1/ 454 (0.2)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	1/ 280 (0.4)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	1/ 530 (0.2)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	1/ 491 (0.2)	0/ 464 (0.0)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	1/ 198 (0.5)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	1/ 448 (0.2)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	1/ 505 (0.2)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G2.4: Anteil an Patient:innen mit schwerer COVID-19 (SARS-CoV-2-Varianten ohne F456L-Mutation)

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	548 (100.0)	525 (100.0)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	0/ 173 (0.0)			
Sex					
Male	0/ 249 (0.0)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	0/ 427 (0.0)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	0/ 262 (0.0)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	0/ 464 (0.0)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	0/ 332 (0.0)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	0/ 368 (0.0)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	0/ 94 (0.0)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	0/ 505 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	548 (100.0)	525 (100.0)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	0/ 173 (0.0)			
Sex					
Male	0/ 249 (0.0)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	0/ 427 (0.0)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	0/ 262 (0.0)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	0/ 464 (0.0)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	0/ 332 (0.0)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	0/ 368 (0.0)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	0/ 94 (0.0)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	0/ 505 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G2.5: Anteil an Patient:innen mit entweder COVID-19-bezogener Hospitalisierung oder Tod

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 90) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	4 (0.8)
Number of censored subjects, n (%)	543 (99.1)	521 (99.2)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	1.21 (0.32, 4.53)	
p-value	0.7791	
Relative Risk (95% CI) [3]	1.16 (0.35, 3.85)	
p-value	0.8126	
Odds Ratio (95% CI) [3]	1.16 (0.34, 3.91)	
p-value	0.8162	
Risk Difference (95% CI) [3]	0.16 (-0.94, 1.27)	
p-value	0.7702	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	1.20 (0.32, 4.44)	
p-value	0.7898	
Relative Risk (95% CI) [3]	1.20 (0.32, 4.44)	
p-value	0.7873	
Odds Ratio (95% CI) [3]	1.20 (0.32, 4.49)	
p-value	0.7873	
Risk Difference (95% CI) [3]	0.15 (-0.94, 1.24)	
p-value	0.7866	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	2/ 360 (0.6)	2/ 352 (0.6)			
>= 65	3/ 188 (1.6)	2/ 173 (1.2)			
Sex					
Male	2/ 249 (0.8)	3/ 274 (1.1)			
Female	3/ 299 (1.0)	1/ 251 (0.4)			
Region					
US	3/ 323 (0.9)	1/ 272 (0.4)			
Europe	2/ 158 (1.3)	3/ 173 (1.7)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	1/ 74 (1.4)	1/ 78 (1.3)			
No	4/ 474 (0.8)	3/ 447 (0.7)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	5/ 524 (1.0)	4/ 498 (0.8)			
AZD7442 use within 12 months prior to randomization					
Yes	2/ 100 (2.0)	0/ 98 (0.0)			
No	3/ 448 (0.7)	4/ 427 (0.9)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	1/ 101 (1.0)			
No	4/ 454 (0.9)	3/ 424 (0.7)			
Solid organ or stem cell transplants					
Yes	3/ 268 (1.1)	3/ 263 (1.1)			
No	2/ 280 (0.7)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	5/ 530 (0.9)	4/ 505 (0.8)			
Taking immunosuppressive medicines					
Yes	5/ 491 (1.0)	3/ 464 (0.6)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	2/ 328 (0.6)	3/ 332 (0.9)			
Abnormal	3/ 184 (1.6)	1/ 171 (0.6)			
Body Mass Index					
<30 kg/m2	1/ 348 (0.3)	3/ 368 (0.8)			
>=30 kg/m2	4/ 198 (2.0)	1/ 151 (0.7)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 90) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	2/ 100 (2.0)	1/ 94 (1.1)			
No	3/ 448 (0.7)	3/ 431 (0.7)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	5/ 525 (1.0)	4/ 505 (0.8)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 180) - Treatment policy strategy
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	6 (1.1)	5 (1.0)
Number of censored subjects, n (%)	542 (98.9)	520 (99.0)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	1.14 (0.35, 3.77)	
p-value	0.8238	
Relative Risk (95% CI) [3]	1.12 (0.37, 3.36)	
p-value	0.8439	
Odds Ratio (95% CI) [3]	1.12 (0.37, 3.41)	
p-value	0.8470	
Risk Difference (95% CI) [3]	0.15 (-1.06, 1.37)	
p-value	0.8077	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	1.14 (0.35, 3.74)	
p-value	0.8268	
Relative Risk (95% CI) [3]	1.15 (0.35, 3.74)	
p-value	0.8170	
Odds Ratio (95% CI) [3]	1.15 (0.35, 3.80)	
p-value	0.8169	
Risk Difference (95% CI) [3]	0.14 (-1.06, 1.35)	
p-value	0.8165	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	2/ 360 (0.6)	3/ 352 (0.9)			
>= 65	4/ 188 (2.1)	2/ 173 (1.2)			
Sex					
Male	3/ 249 (1.2)	4/ 274 (1.5)			
Female	3/ 299 (1.0)	1/ 251 (0.4)			
Region					
US	3/ 323 (0.9)	2/ 272 (0.7)			
Europe	3/ 158 (1.9)	3/ 173 (1.7)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	1/ 74 (1.4)	1/ 78 (1.3)			
No	5/ 474 (1.1)	4/ 447 (0.9)			
Prior SARS-CoV-2 infection within six months prior to randomization					NE
Yes	0/ 24 (0.0)	0/ 27 (0.0)	NE		
No *	6/ 524 (1.1)	5/ 498 (1.0)	1.13 (0.29, 4.70)	1.0000	
AZD7442 use within 12 months prior to randomization					
Yes	2/ 100 (2.0)	0/ 98 (0.0)			
No	4/ 448 (0.9)	5/ 427 (1.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	1/ 101 (1.0)			
No	5/ 454 (1.1)	4/ 424 (0.9)			
Solid organ or stem cell transplants					
Yes	4/ 268 (1.5)	4/ 263 (1.5)			
No	2/ 280 (0.7)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					NE
Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
No *	6/ 530 (1.1)	5/ 505 (1.0)	1.13 (0.29, 4.69)	1.0000	
Taking immunosuppressive medicines					1.0000
Yes *	6/ 491 (1.2)	4/ 464 (0.9)	1.41 (0.33, 6.78)	0.8331	
No **	0/ 57 (0.0)	1/ 61 (1.6)	1.06 (0.00, 41.40)	0.5149	
Electrocardiogram (ECG) interpretation					
Normal	3/ 328 (0.9)	3/ 332 (0.9)			
Abnormal	3/ 184 (1.6)	2/ 171 (1.2)			
Body Mass Index					
<30 kg/m2	1/ 348 (0.3)	4/ 368 (1.1)			
>=30 kg/m2	5/ 198 (2.5)	1/ 151 (0.7)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 180) - Treatment policy strategy - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	2/ 100 (2.0)	1/ 94 (1.1)			
No	4/ 448 (0.9)	4/ 431 (0.9)			
Moderate or severe secondary Immunodeficiency					NE
Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
No *	6/ 525 (1.1)	5/ 505 (1.0)	1.14 (0.29, 4.72)	1.0000	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G3: Weitere Ergebnisse zu Subgruppenanalysen in der Studie SUPERNOVA

Anhang 4-G3.1: Mortalität

Anhang 4-G3.1.1: Gesamtüberleben

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	2 (0.4)	2 (0.4)
Number of censored subjects, n (%)	546 (99.6)	523 (99.6)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified analysis [2]		
Hazard Ratio (95% CI) [3]	0.94 (0.13, 6.69)	
p-value [4]	0.9522	

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Day 90, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Stratified by the randomization factors COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
[3] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[4] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	 Median (95% CI)[1]	Comparator (N=525) n/ N (%)	 Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	 p-Value[3]	Interaction p-Value[4]
Age							
< 65	2/ 360 (0.6)		1/ 352 (0.3)				
>= 65	0/ 188 (0.0)		1/ 173 (0.6)				
Sex							
Male	1/ 249 (0.4)		2/ 274 (0.7)				
Female	1/ 299 (0.3)		0/ 251 (0.0)				
Region							
US	1/ 323 (0.3)		0/ 272 (0.0)				
Europe	1/ 158 (0.6)		1/ 173 (0.6)				
Other	0/ 67 (0.0)		1/ 80 (1.3)				
COVID-19 vaccination status within six months prior to randomization							
Yes	0/ 74 (0.0)		1/ 78 (1.3)				
No	2/ 474 (0.4)		1/ 447 (0.2)				
Prior SARS-CoV-2 infection within six months prior to randomization							
Yes	0/ 24 (0.0)		0/ 27 (0.0)				
No	2/ 524 (0.4)		2/ 498 (0.4)				
AZD7442 use within 12 months prior to randomization							
Yes	0/ 100 (0.0)		0/ 98 (0.0)				
No	2/ 448 (0.4)		2/ 427 (0.5)				
Prior COVID-19 vaccination or prior SARS-CoV-2 infection							
Yes	0/ 94 (0.0)		1/ 101 (1.0)				
No	2/ 454 (0.4)		1/ 424 (0.2)				
Solid organ or stem cell transplants							
Yes	1/ 268 (0.4)		0/ 263 (0.0)				
No	1/ 280 (0.4)		2/ 262 (0.8)				
Solid tumor cancer and on active treatment							
Yes	1/ 18 (5.6)		0/ 20 (0.0)				
No	1/ 530 (0.2)		2/ 505 (0.4)				
Taking immunosuppressive medicines							
Yes	2/ 491 (0.4)		1/ 464 (0.2)				
No	0/ 57 (0.0)		1/ 61 (1.6)				
Electrocardiogram (ECG) interpretation							
Normal	1/ 328 (0.3)		1/ 332 (0.3)				
Abnormal	1/ 184 (0.5)		0/ 171 (0.0)				
Body Mass Index							
<30 kg/m2	1/ 348 (0.3)		2/ 368 (0.5)				
>=30 kg/m2	1/ 198 (0.5)		0/ 151 (0.0)				

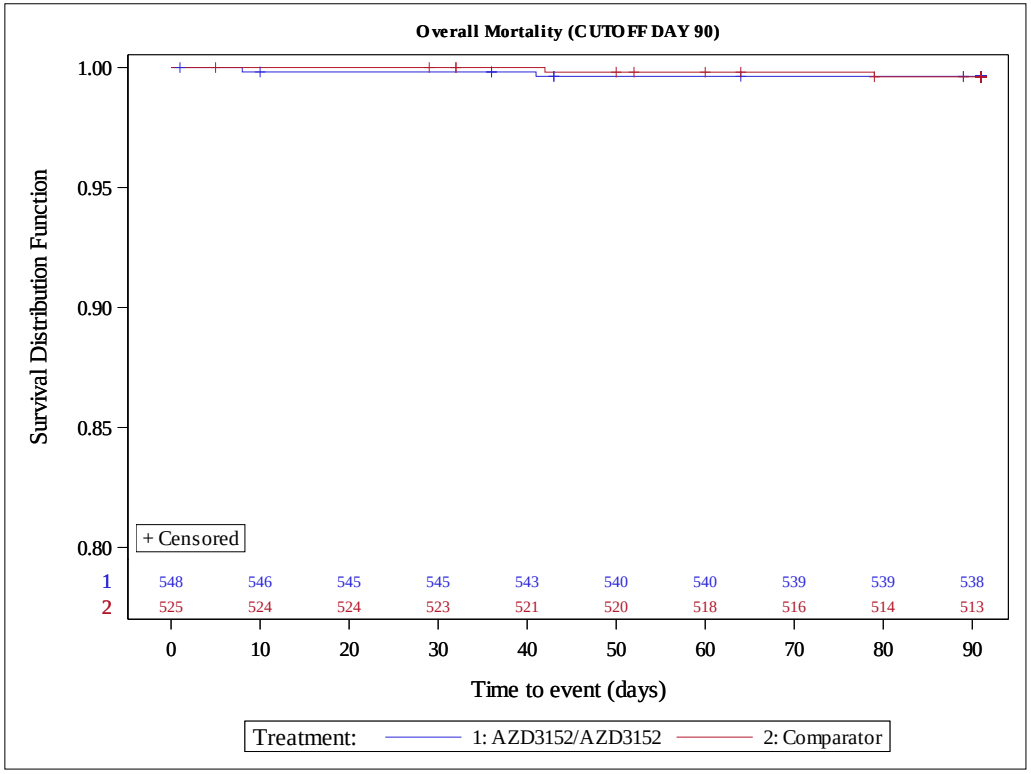
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	 Median (95% CI)[1]	Comparator (N=525) n/ N (%)	 Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	 p-Value[3]	Interaction p-Value[4]
Hematological malignancies							
Yes	1/ 100 (1.0)		2/ 94 (2.1)				
No	1/ 448 (0.2)		0/ 431 (0.0)				
Moderate or severe secondary Immunodeficiency							
Yes	0/ 23 (0.0)		0/ 20 (0.0)				
No	2/ 525 (0.4)		2/ 505 (0.4)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Kaplan Meier Plot of Overall Mortality (CUTOFF DAY 90)
Full pre-exposure analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	3 (0.5)	3 (0.6)
Number of censored subjects, n (%)	545 (99.5)	522 (99.4)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified analysis [2]		
Hazard Ratio (95% CI) [3]	0.94 (0.19, 4.64)	
p-value [4]	0.9362	

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Day 180, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Stratified by the randomization factors COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
[3] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[4] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup	AZD3152/AZD3152 (N=548)		Comparator (N=525)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 65	2/ 360 (0.6)		1/ 352 (0.3)				
>= 65	1/ 188 (0.5)		2/ 173 (1.2)				
Sex							
Male	2/ 249 (0.8)		3/ 274 (1.1)				
Female	1/ 299 (0.3)		0/ 251 (0.0)				
Region							
US	2/ 323 (0.6)		0/ 272 (0.0)				
Europe	1/ 158 (0.6)		2/ 173 (1.2)				
Other	0/ 67 (0.0)		1/ 80 (1.3)				
COVID-19 vaccination status within six months prior to randomization							
Yes	0/ 74 (0.0)		1/ 78 (1.3)				
No	3/ 474 (0.6)		2/ 447 (0.4)				
Prior SARS-CoV-2 infection within six months prior to randomization							
Yes	0/ 24 (0.0)		0/ 27 (0.0)				
No	3/ 524 (0.6)		3/ 498 (0.6)				
AZD7442 use within 12 months prior to randomization							
Yes	0/ 100 (0.0)		0/ 98 (0.0)				
No	3/ 448 (0.7)		3/ 427 (0.7)				
Prior COVID-19 vaccination or prior SARS-CoV-2 infection							
Yes	0/ 94 (0.0)		1/ 101 (1.0)				
No	3/ 454 (0.7)		2/ 424 (0.5)				
Solid organ or stem cell transplants							
Yes	1/ 268 (0.4)		1/ 263 (0.4)				
No	2/ 280 (0.7)		2/ 262 (0.8)				
Solid tumor cancer and on active treatment							
Yes	2/ 18 (11.1)		0/ 20 (0.0)				
No	1/ 530 (0.2)		3/ 505 (0.6)				
Taking immunosuppressive medicines							
Yes	3/ 491 (0.6)		2/ 464 (0.4)				
No	0/ 57 (0.0)		1/ 61 (1.6)				
Electrocardiogram (ECG) interpretation							
Normal	1/ 328 (0.3)		1/ 332 (0.3)				
Abnormal	2/ 184 (1.1)		1/ 171 (0.6)				
Body Mass Index							
<30 kg/m2	2/ 348 (0.6)		3/ 368 (0.8)				
>=30 kg/m2	1/ 198 (0.5)		0/ 151 (0.0)				

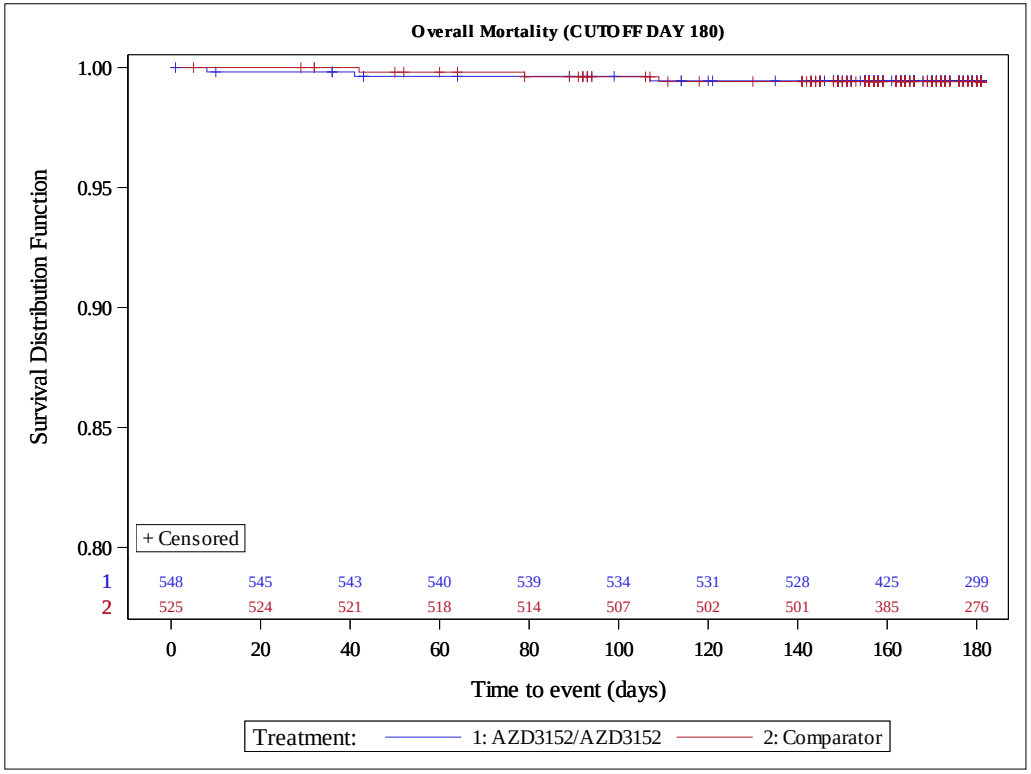
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	 Median (95% CI)[1]	Comparator (N=525) n/ N (%)	 Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	 p-Value[3]	Interaction p-Value[4]
Hematological malignancies							
Yes	1/ 100 (1.0)		3/ 94 (3.2)				
No	2/ 448 (0.4)		0/ 431 (0.0)				
Moderate or severe secondary Immunodeficiency							
Yes	0/ 23 (0.0)		0/ 20 (0.0)				
No	3/ 525 (0.6)		3/ 505 (0.6)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Kaplan Meier Plot of Overall Mortality (CUTOFF DAY 180)
Full pre-exposure analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

Anhang 4-G3.1.2: Gesamtüberleben (Todesfälle mit COVID-19-Bezug)

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified analysis [2]		
Hazard Ratio (95% CI) [3]	NE	
p-value [4]		

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Day 90, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Stratified by the randomization factors COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
[3] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[4] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	AZD3152/AZD3152 (N=548) Median (95% CI)[1]	Comparator (N=525) n/ N (%)	Comparator (N=525) Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	Unstratified analysis p-Value[3]	Interaction p-Value[4]
Age							
< 65	0/ 360 (0.0)		0/ 352 (0.0)				
>= 65	0/ 188 (0.0)		1/ 173 (0.6)				
Sex							
Male	0/ 249 (0.0)		1/ 274 (0.4)				
Female	0/ 299 (0.0)		0/ 251 (0.0)				
Region							
US	0/ 323 (0.0)		0/ 272 (0.0)				
Europe	0/ 158 (0.0)		1/ 173 (0.6)				
Other	0/ 67 (0.0)		0/ 80 (0.0)				
COVID-19 vaccination status within six months prior to randomization							
Yes	0/ 74 (0.0)		1/ 78 (1.3)				
No	0/ 474 (0.0)		0/ 447 (0.0)				
Prior SARS-CoV-2 infection within six months prior to randomization							
Yes	0/ 24 (0.0)		0/ 27 (0.0)				
No	0/ 524 (0.0)		1/ 498 (0.2)				
AZD7442 use within 12 months prior to randomization							
Yes	0/ 100 (0.0)		0/ 98 (0.0)				
No	0/ 448 (0.0)		1/ 427 (0.2)				
Prior COVID-19 vaccination or prior SARS-CoV-2 infection							
Yes	0/ 94 (0.0)		1/ 101 (1.0)				
No	0/ 454 (0.0)		0/ 424 (0.0)				
Solid organ or stem cell transplants							
Yes	0/ 268 (0.0)		0/ 263 (0.0)				
No	0/ 280 (0.0)		1/ 262 (0.4)				
Solid tumor cancer and on active treatment							
Yes	0/ 18 (0.0)		0/ 20 (0.0)				
No	0/ 530 (0.0)		1/ 505 (0.2)				
Taking immunosuppressive medicines							
Yes	0/ 491 (0.0)		0/ 464 (0.0)				
No	0/ 57 (0.0)		1/ 61 (1.6)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 328 (0.0)		1/ 332 (0.3)				
Abnormal	0/ 184 (0.0)		0/ 171 (0.0)				
Body Mass Index							
<30 kg/m2	0/ 348 (0.0)		1/ 368 (0.3)				
>=30 kg/m2	0/ 198 (0.0)		0/ 151 (0.0)				

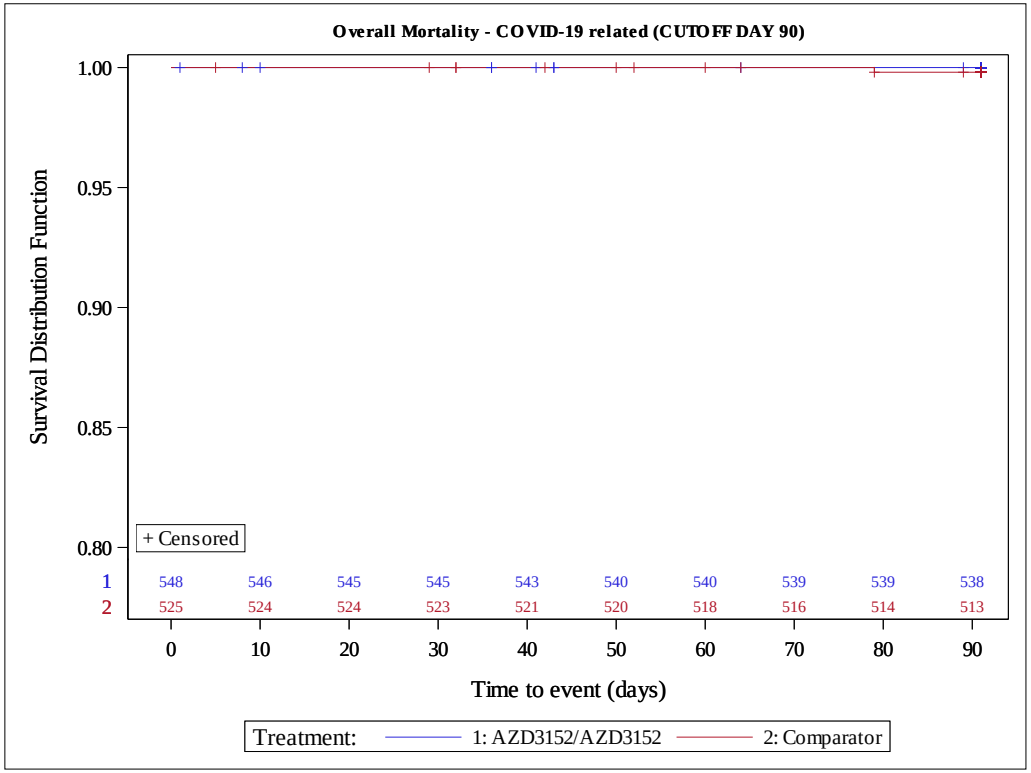
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	 Median (95% CI)[1]	Comparator (N=525) n/ N (%)	 Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	 p-Value[3]	Interaction p-Value[4]
Hematological malignancies							
Yes	0/ 100 (0.0)		1/ 94 (1.1)				
No	0/ 448 (0.0)		0/ 431 (0.0)				
Moderate or severe secondary Immunodeficiency							
Yes	0/ 23 (0.0)		0/ 20 (0.0)				
No	0/ 525 (0.0)		1/ 505 (0.2)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Kaplan Meier Plot of Overall Mortality - COVID-19 related (CUTOFF DAY 90)
Full pre-exposure analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Stratified analysis [2]		
Hazard Ratio (95% CI) [3]	NE	
p-value [4]		

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Day 180, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Stratified by the randomization factors COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
[3] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[4] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	AZD3152/AZD3152 (N=548) Median (95% CI)[1]	Comparator (N=525) n/ N (%)	Comparator (N=525) Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	Unstratified analysis p-Value[3]	Interaction p-Value[4]
Age							
< 65	0/ 360 (0.0)		0/ 352 (0.0)				
>= 65	0/ 188 (0.0)		1/ 173 (0.6)				
Sex							
Male	0/ 249 (0.0)		1/ 274 (0.4)				
Female	0/ 299 (0.0)		0/ 251 (0.0)				
Region							
US	0/ 323 (0.0)		0/ 272 (0.0)				
Europe	0/ 158 (0.0)		1/ 173 (0.6)				
Other	0/ 67 (0.0)		0/ 80 (0.0)				
COVID-19 vaccination status within six months prior to randomization							
Yes	0/ 74 (0.0)		1/ 78 (1.3)				
No	0/ 474 (0.0)		0/ 447 (0.0)				
Prior SARS-CoV-2 infection within six months prior to randomization							
Yes	0/ 24 (0.0)		0/ 27 (0.0)				
No	0/ 524 (0.0)		1/ 498 (0.2)				
AZD7442 use within 12 months prior to randomization							
Yes	0/ 100 (0.0)		0/ 98 (0.0)				
No	0/ 448 (0.0)		1/ 427 (0.2)				
Prior COVID-19 vaccination or prior SARS-CoV-2 infection							
Yes	0/ 94 (0.0)		1/ 101 (1.0)				
No	0/ 454 (0.0)		0/ 424 (0.0)				
Solid organ or stem cell transplants							
Yes	0/ 268 (0.0)		0/ 263 (0.0)				
No	0/ 280 (0.0)		1/ 262 (0.4)				
Solid tumor cancer and on active treatment							
Yes	0/ 18 (0.0)		0/ 20 (0.0)				
No	0/ 530 (0.0)		1/ 505 (0.2)				
Taking immunosuppressive medicines							
Yes	0/ 491 (0.0)		0/ 464 (0.0)				
No	0/ 57 (0.0)		1/ 61 (1.6)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 328 (0.0)		1/ 332 (0.3)				
Abnormal	0/ 184 (0.0)		0/ 171 (0.0)				
Body Mass Index							
<30 kg/m2	0/ 348 (0.0)		1/ 368 (0.3)				
>=30 kg/m2	0/ 198 (0.0)		0/ 151 (0.0)				

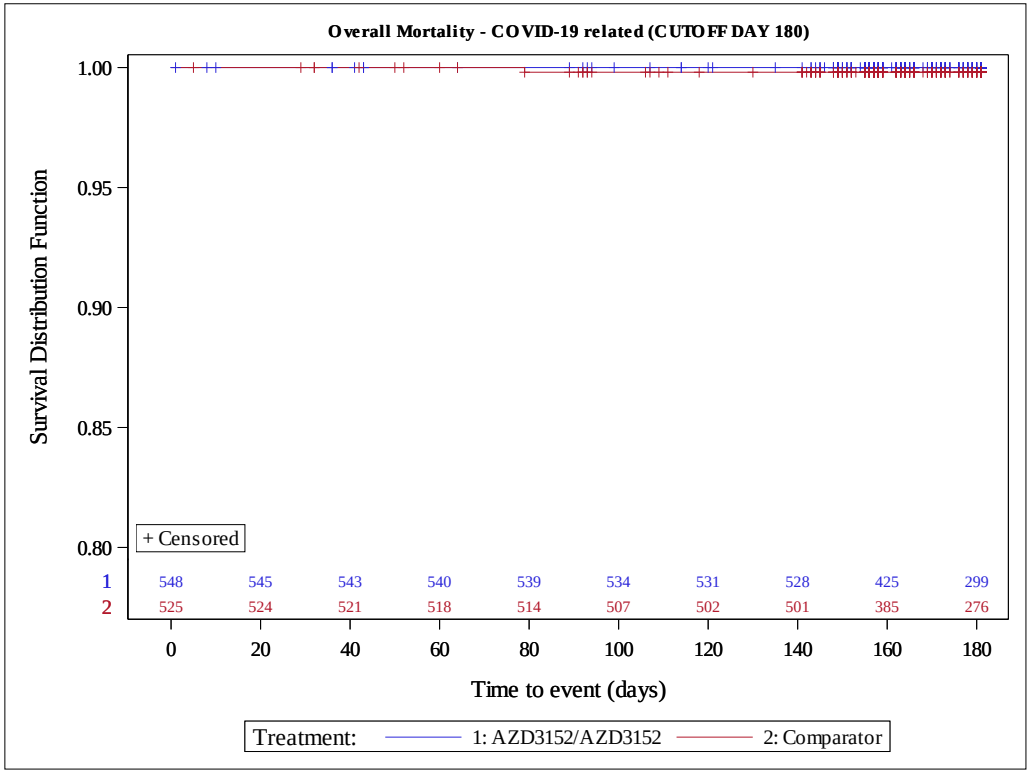
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	 Median (95% CI)[1]	Comparator (N=525) n/ N (%)	 Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	 p-Value[3]	Interaction p-Value[4]
Hematological malignancies							
Yes	0/ 100 (0.0)		1/ 94 (1.1)				
No	0/ 448 (0.0)		0/ 431 (0.0)				
Moderate or severe secondary Immunodeficiency							
Yes	0/ 23 (0.0)		0/ 20 (0.0)				
No	0/ 525 (0.0)		1/ 505 (0.2)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152/AZD3152 compared to Comparator.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Kaplan Meier Plot of Overall Mortality - COVID-19 related (CUTOFF DAY 180)
Full pre-exposure analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

Anhang 4-G3.2: Symptomspezifische Wirksamkeit

Anhang 4-G3.2.1: Anteil an Patient:innen mit symptomatischer COVID-19

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	20 (3.6)	44 (8.4)
Number of censored subjects, n (%)	528 (96.4)	481 (91.6)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.42 (0.25, 0.72)	
p-value	0.0014	
Relative Risk (95% CI) [3]	0.48 (0.29, 0.81)	
p-value	0.0053	
Odds Ratio (95% CI) [3]	0.46 (0.27, 0.79)	
p-value	0.0049	
Risk Difference (95% CI) [3]	-4.76 (-7.61, -1.92)	
p-value	0.0010	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.43 (0.25, 0.73)	
p-value	0.0016	
Relative Risk (95% CI) [3]	0.44 (0.26, 0.73)	
p-value	0.0016	
Odds Ratio (95% CI) [3]	0.41 (0.24, 0.71)	
p-value	0.0015	
Risk Difference (95% CI) [3]	-4.73 (-7.57, -1.89)	
p-value	0.0011	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.7666
< 65	15/ 360 (4.2)	32/ 352 (9.1)	0.45 (0.24, 0.83)	0.0109	
>= 65	5/ 188 (2.7)	12/ 173 (6.9)	0.38 (0.13, 1.07)	0.0656	
Sex					0.5059
Male	7/ 249 (2.8)	22/ 274 (8.0)	0.34 (0.15, 0.80)	0.0131	
Female	13/ 299 (4.3)	22/ 251 (8.8)	0.49 (0.25, 0.98)	0.0426	
Region					0.4196
US	13/ 323 (4.0)	18/ 272 (6.6)	0.61 (0.30, 1.24)	0.1679	
Europe	5/ 158 (3.2)	16/ 173 (9.2)	0.33 (0.12, 0.91)	0.0318	
Other	2/ 67 (3.0)	10/ 80 (12.5)	0.23 (0.05, 1.05)	0.0586	
COVID-19 vaccination status within six months prior to randomization					0.7938
Yes	3/ 74 (4.1)	6/ 78 (7.7)	0.51 (0.13, 2.05)	0.3413	
No	17/ 474 (3.6)	38/ 447 (8.5)	0.42 (0.24, 0.74)	0.0026	
Prior SARS-CoV-2 infection within six months prior to randomization					1.0000
Yes **	0/ 24 (0.0)	1/ 27 (3.7)	1.08 (0.00, 42.02)	0.5186	
No *	20/ 524 (3.8)	43/ 498 (8.6)	0.44 (0.24, 0.76)	0.0022	
AZD7442 use within 12 months prior to randomization					0.2734
Yes	1/ 100 (1.0)	7/ 98 (7.1)	0.14 (0.02, 1.16)	0.0684	
No	19/ 448 (4.2)	37/ 427 (8.7)	0.48 (0.28, 0.83)	0.0088	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.9510
Yes	3/ 94 (3.2)	7/ 101 (6.9)	0.44 (0.11, 1.72)	0.2408	
No	17/ 454 (3.7)	37/ 424 (8.7)	0.42 (0.24, 0.75)	0.0034	
Solid organ or stem cell transplants					0.8189
Yes	10/ 268 (3.7)	21/ 263 (8.0)	0.46 (0.21, 0.97)	0.0414	
No	10/ 280 (3.6)	23/ 262 (8.8)	0.40 (0.19, 0.84)	0.0161	
Solid tumor cancer and on active treatment					0.5438
Yes **	1/ 18 (5.6)	0/ 20 (0.0)	1.27 (0.03, I)	0.4407	
No *	19/ 530 (3.6)	44/ 505 (8.7)	0.40 (0.22, 0.70)	0.0008	
Taking immunosuppressive medicines					0.7014
Yes	19/ 491 (3.9)	40/ 464 (8.6)	0.44 (0.25, 0.75)	0.0030	
No	1/ 57 (1.8)	4/ 61 (6.6)	0.28 (0.03, 2.51)	0.2559	
Electrocardiogram (ECG) interpretation					0.0268
Normal	12/ 328 (3.7)	36/ 332 (10.8)	0.32 (0.17, 0.62)	0.0006	
Abnormal	8/ 184 (4.3)	6/ 171 (3.5)	1.31 (0.45, 3.77)	0.6198	
Body Mass Index					0.7179
<30 kg/m2	15/ 348 (4.3)	32/ 368 (8.7)	0.48 (0.26, 0.89)	0.0199	
>=30 kg/m2	5/ 198 (2.5)	10/ 151 (6.6)	0.39 (0.13, 1.13)	0.0820	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.7774
Yes	4/ 100 (4.0)	10/ 94 (10.6)	0.37 (0.12, 1.17)	0.0895	
No	16/ 448 (3.6)	34/ 431 (7.9)	0.45 (0.25, 0.81)	0.0076	
Moderate or severe secondary Immunodeficiency					0.5870
Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.92 (0.06, 15.05)	0.9520	
No	19/ 525 (3.6)	43/ 505 (8.5)	0.42 (0.24, 0.71)	0.0015	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	39 (7.1)	58 (11.0)
Number of censored subjects, n (%)	509 (92.9)	467 (89.0)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.62 (0.41, 0.93)	
p-value	0.0197	
Relative Risk (95% CI) [3]	0.66 (0.45, 0.97)	
p-value	0.0360	
Odds Ratio (95% CI) [3]	0.63 (0.41, 0.96)	
p-value	0.0332	
Risk Difference (95% CI) [3]	-4.07 (-7.51, -0.63)	
p-value	0.0204	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.62 (0.41, 0.93)	
p-value	0.0214	
Relative Risk (95% CI) [3]	0.64 (0.44, 0.95)	
p-value	0.0263	
Odds Ratio (95% CI) [3]	0.62 (0.40, 0.94)	
p-value	0.0259	
Risk Difference (95% CI) [3]	-3.93 (-7.37, -0.49)	
p-value	0.0251	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.6901
< 65	30/ 360 (8.3)	43/ 352 (12.2)	0.65 (0.41, 1.04)	0.0735	
>= 65	9/ 188 (4.8)	15/ 173 (8.7)	0.54 (0.24, 1.23)	0.1425	
Sex					0.4698
Male	15/ 249 (6.0)	30/ 274 (10.9)	0.52 (0.28, 0.97)	0.0386	
Female	24/ 299 (8.0)	28/ 251 (11.2)	0.71 (0.41, 1.22)	0.2121	
Region					0.3547
US	25/ 323 (7.7)	26/ 272 (9.6)	0.80 (0.46, 1.39)	0.4324	
Europe	11/ 158 (7.0)	21/ 173 (12.1)	0.53 (0.26, 1.11)	0.0918	
Other	3/ 67 (4.5)	11/ 80 (13.8)	0.31 (0.09, 1.13)	0.0766	
COVID-19 vaccination status within six months prior to randomization					0.9491
Yes	4/ 74 (5.4)	6/ 78 (7.7)	0.64 (0.18, 2.32)	0.5015	
No	35/ 474 (7.4)	52/ 447 (11.6)	0.62 (0.40, 0.95)	0.0271	
Prior SARS-CoV-2 infection within six months prior to randomization					0.6031
Yes	1/ 24 (4.2)	3/ 27 (11.1)	0.35 (0.04, 3.26)	0.3538	
No	38/ 524 (7.3)	55/ 498 (11.0)	0.63 (0.42, 0.96)	0.0309	
AZD7442 use within 12 months prior to randomization					0.4071
Yes	4/ 100 (4.0)	10/ 98 (10.2)	0.39 (0.12, 1.25)	0.1136	
No	35/ 448 (7.8)	48/ 427 (11.2)	0.66 (0.43, 1.03)	0.0657	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.8145
Yes	5/ 94 (5.3)	9/ 101 (8.9)	0.55 (0.18, 1.64)	0.2834	
No	34/ 454 (7.5)	49/ 424 (11.6)	0.63 (0.41, 0.98)	0.0395	
Solid organ or stem cell transplants					0.7662
Yes	19/ 268 (7.1)	27/ 263 (10.3)	0.66 (0.37, 1.19)	0.1692	
No	20/ 280 (7.1)	31/ 262 (11.8)	0.58 (0.33, 1.03)	0.0617	
Solid tumor cancer and on active treatment					0.6853
Yes **	1/ 18 (5.6)	0/ 20 (0.0)	1.28 (0.03, I)	0.4388	
No *	38/ 530 (7.2)	58/ 505 (11.5)	0.60 (0.39, 0.91)	0.0162	
Taking immunosuppressive medicines					0.5728
Yes	37/ 491 (7.5)	52/ 464 (11.2)	0.64 (0.42, 0.97)	0.0355	
No	2/ 57 (3.5)	6/ 61 (9.8)	0.39 (0.08, 1.96)	0.2556	
Electrocardiogram (ECG) interpretation					0.2877
Normal	26/ 328 (7.9)	43/ 332 (13.0)	0.56 (0.34, 0.91)	0.0198	
Abnormal	12/ 184 (6.5)	13/ 171 (7.6)	0.92 (0.42, 2.03)	0.8438	
Body Mass Index					0.3202
<30 kg/m2	24/ 348 (6.9)	44/ 368 (12.0)	0.55 (0.34, 0.91)	0.0198	
>=30 kg/m2	14/ 198 (7.1)	12/ 151 (7.9)	0.88 (0.41, 1.90)	0.7443	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.3014
Yes	5/ 100 (5.0)	12/ 94 (12.8)	0.38 (0.13, 1.07)	0.0677	
No	34/ 448 (7.6)	46/ 431 (10.7)	0.69 (0.44, 1.07)	0.0952	
Moderate or severe secondary Immunodeficiency					0.7654
Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.95 (0.06, 15.91)	0.9706	
No	38/ 525 (7.2)	57/ 505 (11.3)	0.61 (0.41, 0.93)	0.0201	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G3.2.2: Anteil an Patient:innen mit symptomatischer COVID-19 (SARS-CoV-2-Varianten ohne F456L-Mutation)

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	3 (0.5)	20 (3.8)
Number of censored subjects, n (%)	545 (99.5)	505 (96.2)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.14 (0.04, 0.47)	
p-value	0.0014	
Relative Risk (95% CI) [3]	0.21 (0.08, 0.59)	
p-value	0.0027	
Odds Ratio (95% CI) [3]	0.20 (0.07, 0.57)	
p-value	0.0025	
Risk Difference (95% CI) [3]	-3.27 (-5.02, -1.52)	
p-value	0.0003	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.14 (0.04, 0.47)	
p-value	0.0015	
Relative Risk (95% CI) [3]	0.14 (0.04, 0.48)	
p-value	0.0016	
Odds Ratio (95% CI) [3]	0.14 (0.04, 0.47)	
p-value	0.0015	
Risk Difference (95% CI) [3]	-3.26 (-5.01, -1.51)	
p-value	0.0003	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					1.0000
< 65 *	3/ 360 (0.8)	15/ 352 (4.3)	0.19 (0.04, 0.68)	0.0059	
>= 65 **	0/ 188 (0.0)	5/ 173 (2.9)	0.13 (0.00, 0.98)	0.0240	
Sex					0.4692
Male	2/ 249 (0.8)	10/ 274 (3.6)	0.21 (0.05, 0.98)	0.0465	
Female	1/ 299 (0.3)	10/ 251 (4.0)	0.08 (0.01, 0.65)	0.0177	
Region					0.8734
US *	2/ 323 (0.6)	3/ 272 (1.1)	0.56 (0.05, 4.88)	0.8360	
Europe **	0/ 158 (0.0)	10/ 173 (5.8)	0.08 (0.00, 0.48)	0.0013	
Other *	1/ 67 (1.5)	7/ 80 (8.8)	0.17 (0.00, 1.30)	0.1121	
COVID-19 vaccination status within six months prior to randomization					1.0000
Yes **	0/ 74 (0.0)	2/ 78 (2.6)	0.42 (0.00, 5.42)	0.2545	
No *	3/ 474 (0.6)	18/ 447 (4.0)	0.16 (0.03, 0.53)	0.0009	
Prior SARS-CoV-2 infection within six months prior to randomization					1.0000
Yes **	0/ 24 (0.0)	1/ 27 (3.7)	1.08 (0.00, 42.02)	0.5186	
No *	3/ 524 (0.6)	19/ 498 (3.8)	0.15 (0.03, 0.50)	0.0005	
AZD7442 use within 12 months prior to randomization					1.0000
Yes **	0/ 100 (0.0)	4/ 98 (4.1)	0.19 (0.00, 1.51)	0.0620	
No *	3/ 448 (0.7)	16/ 427 (3.7)	0.17 (0.03, 0.61)	0.0027	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					1.0000
Yes **	0/ 94 (0.0)	3/ 101 (3.0)	0.27 (0.00, 2.51)	0.1318	
No *	3/ 454 (0.7)	17/ 424 (4.0)	0.16 (0.03, 0.56)	0.0014	
Solid organ or stem cell transplants					0.6117
Yes	1/ 268 (0.4)	10/ 263 (3.8)	0.10 (0.01, 0.75)	0.0251	
No	2/ 280 (0.7)	10/ 262 (3.8)	0.19 (0.04, 0.84)	0.0293	
Solid tumor cancer and on active treatment					NE
Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
No *	3/ 530 (0.6)	20/ 505 (4.0)	0.14 (0.03, 0.47)	0.0003	
Taking immunosuppressive medicines					1.0000
Yes *	3/ 491 (0.6)	19/ 464 (4.1)	0.15 (0.03, 0.49)	0.0004	
No **	0/ 57 (0.0)	1/ 61 (1.6)	1.13 (0.00, 43.88)	0.5295	
Electrocardiogram (ECG) interpretation					0.6311
Normal	2/ 328 (0.6)	15/ 332 (4.5)	0.13 (0.03, 0.56)	0.0062	
Abnormal	1/ 184 (0.5)	4/ 171 (2.3)	0.25 (0.03, 2.20)	0.2088	
Body Mass Index					1.0000
<30 kg/m2 *	3/ 348 (0.9)	14/ 368 (3.8)	0.22 (0.04, 0.79)	0.0152	
>=30 kg/m2 **	0/ 198 (0.0)	6/ 151 (4.0)	0.09 (0.00, 0.65)	0.0068	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.6174
Yes	1/ 100 (1.0)	4/ 94 (4.3)	0.23 (0.03, 2.03)	0.1865	
No	2/ 448 (0.4)	16/ 431 (3.7)	0.12 (0.03, 0.51)	0.0044	
Moderate or severe secondary Immunodeficiency					NE
Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
No *	3/ 525 (0.6)	20/ 505 (4.0)	0.14 (0.03, 0.48)	0.0003	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	19 (3.5)	27 (5.1)
Number of censored subjects, n (%)	529 (96.5)	498 (94.9)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.65 (0.36, 1.16)	
p-value	0.1418	
Relative Risk (95% CI) [3]	0.72 (0.40, 1.29)	
p-value	0.2699	
Odds Ratio (95% CI) [3]	0.71 (0.38, 1.30)	
p-value	0.2641	
Risk Difference (95% CI) [3]	-1.73 (-4.16, 0.71)	
p-value	0.1649	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.65 (0.36, 1.16)	
p-value	0.1469	
Relative Risk (95% CI) [3]	0.67 (0.38, 1.20)	
p-value	0.1786	
Odds Ratio (95% CI) [3]	0.66 (0.36, 1.21)	
p-value	0.1782	
Risk Difference (95% CI) [3]	-1.68 (-4.11, 0.76)	
p-value	0.1769	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					0.8777
< 65	15/ 360 (4.2)	21/ 352 (6.0)	0.67 (0.35, 1.29)	0.2302	
>= 65	4/ 188 (2.1)	6/ 173 (3.5)	0.60 (0.17, 2.11)	0.4237	
Sex					0.7921
Male	8/ 249 (3.2)	14/ 274 (5.1)	0.59 (0.25, 1.41)	0.2383	
Female	11/ 299 (3.7)	13/ 251 (5.2)	0.70 (0.31, 1.55)	0.3752	
Region					0.0623
US	12/ 323 (3.7)	6/ 272 (2.2)	1.67 (0.63, 4.42)	0.3026	
Europe	5/ 158 (3.2)	14/ 173 (8.1)	0.36 (0.13, 1.00)	0.0499	
Other	2/ 67 (3.0)	7/ 80 (8.8)	0.33 (0.07, 1.59)	0.1657	
COVID-19 vaccination status within six months prior to randomization					0.8044
Yes	1/ 74 (1.4)	2/ 78 (2.6)	0.48 (0.04, 5.26)	0.5506	
No	18/ 474 (3.8)	25/ 447 (5.6)	0.66 (0.36, 1.20)	0.1759	
Prior SARS-CoV-2 infection within six months prior to randomization					1.0000
Yes **	0/ 24 (0.0)	3/ 27 (11.1)	0.27 (0.00, 2.51)	0.1319	
No *	19/ 524 (3.6)	24/ 498 (4.8)	0.73 (0.38, 1.38)	0.3708	
AZD7442 use within 12 months prior to randomization					0.1639
Yes	1/ 100 (1.0)	6/ 98 (6.1)	0.16 (0.02, 1.35)	0.0922	
No	18/ 448 (4.0)	21/ 427 (4.9)	0.78 (0.42, 1.46)	0.4365	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.2409
Yes	1/ 94 (1.1)	5/ 101 (5.0)	0.20 (0.02, 1.66)	0.1356	
No	18/ 454 (4.0)	22/ 424 (5.2)	0.74 (0.40, 1.38)	0.3504	
Solid organ or stem cell transplants					0.9928
Yes	9/ 268 (3.4)	13/ 263 (4.9)	0.65 (0.28, 1.51)	0.3191	
No	10/ 280 (3.6)	14/ 262 (5.3)	0.65 (0.29, 1.45)	0.2912	
Solid tumor cancer and on active treatment					NE
Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
No *	19/ 530 (3.6)	27/ 505 (5.3)	0.64 (0.34, 1.20)	0.1764	
Taking immunosuppressive medicines					0.9471
Yes	18/ 491 (3.7)	25/ 464 (5.4)	0.64 (0.35, 1.17)	0.1509	
No	1/ 57 (1.8)	2/ 61 (3.3)	0.59 (0.05, 6.47)	0.6672	
Electrocardiogram (ECG) interpretation					0.8593
Normal	13/ 328 (4.0)	19/ 332 (5.7)	0.63 (0.31, 1.28)	0.2018	
Abnormal	5/ 184 (2.7)	7/ 171 (4.1)	0.72 (0.23, 2.24)	0.5648	
Body Mass Index					0.4529
<30 kg/m2	10/ 348 (2.9)	19/ 368 (5.2)	0.53 (0.25, 1.14)	0.1061	
>=30 kg/m2	9/ 198 (4.5)	8/ 151 (5.3)	0.85 (0.33, 2.18)	0.7325	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of symptomatic COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					0.2960
Yes	2/ 100 (2.0)	6/ 94 (6.4)	0.30 (0.06, 1.48)	0.1395	
No	17/ 448 (3.8)	21/ 431 (4.9)	0.75 (0.40, 1.42)	0.3768	
Moderate or severe secondary Immunodeficiency					NE
Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
No *	19/ 525 (3.6)	27/ 505 (5.3)	0.65 (0.34, 1.21)	0.1903	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G3.2.3: Anteil an Patient:innen mit schwerer COVID-19

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Number of censored subjects, n (%)	547 (99.8)	524 (99.8)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.98 (0.07, 14.79)	
p-value	0.9892	
Relative Risk (95% CI) [3]	0.95 (0.10, 9.05)	
p-value	0.9645	
Odds Ratio (95% CI) [3]	0.95 (0.10, 9.26)	
p-value	0.9680	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9745	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.95 (0.06, 15.19)	
p-value	0.9721	
Relative Risk (95% CI) [3]	0.96 (0.06, 15.28)	
p-value	0.9758	
Odds Ratio (95% CI) [3]	0.96 (0.06, 15.35)	
p-value	0.9758	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9758	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	1/ 188 (0.5)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	1/ 299 (0.3)	0/ 251 (0.0)			
Region					
US	1/ 323 (0.3)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	1/ 78 (1.3)			
No	1/ 474 (0.2)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	1/ 524 (0.2)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	1/ 448 (0.2)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	1/ 101 (1.0)			
No	1/ 454 (0.2)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	1/ 280 (0.4)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	1/ 530 (0.2)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	1/ 491 (0.2)	0/ 464 (0.0)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	1/ 198 (0.5)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	1/ 448 (0.2)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	1/ 505 (0.2)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Number of censored subjects, n (%)	547 (99.8)	524 (99.8)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.95 (0.06, 14.91)	
p-value	0.9728	
Relative Risk (95% CI) [3]	0.95 (0.10, 9.05)	
p-value	0.9645	
Odds Ratio (95% CI) [3]	0.95 (0.10, 9.26)	
p-value	0.9680	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9745	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.94 (0.06, 15.05)	
p-value	0.9659	
Relative Risk (95% CI) [3]	0.96 (0.06, 15.28)	
p-value	0.9758	
Odds Ratio (95% CI) [3]	0.96 (0.06, 15.35)	
p-value	0.9758	
Risk Difference (95% CI) [3]	-0.01 (-0.52, 0.51)	
p-value	0.9758	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	1/ 188 (0.5)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	1/ 299 (0.3)	0/ 251 (0.0)			
Region					
US	1/ 323 (0.3)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	1/ 78 (1.3)			
No	1/ 474 (0.2)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	1/ 524 (0.2)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	1/ 448 (0.2)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	1/ 101 (1.0)			
No	1/ 454 (0.2)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	1/ 280 (0.4)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	1/ 530 (0.2)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	1/ 491 (0.2)	0/ 464 (0.0)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	1/ 198 (0.5)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	1/ 448 (0.2)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	1/ 505 (0.2)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G3.2.4: Anteil an Patient:innen mit schwerer COVID-19 (SARS-CoV-2-Varianten ohne F456L-Mutation)

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	548 (100.0)	525 (100.0)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	0/ 173 (0.0)			
Sex					
Male	0/ 249 (0.0)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	0/ 427 (0.0)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	0/ 262 (0.0)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	0/ 464 (0.0)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	0/ 332 (0.0)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	0/ 368 (0.0)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	0/ 94 (0.0)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	0/ 505 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	548 (100.0)	525 (100.0)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	NE	
p-value		
Relative Risk (95% CI) [3]	NE	
p-value		
Odds Ratio (95% CI) [3]	NE	
p-value		
Risk Difference (95% CI) [3]	NE	
p-value		

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification for Possion regression and others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	0/ 173 (0.0)			
Sex					
Male	0/ 249 (0.0)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	0/ 427 (0.0)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	0/ 262 (0.0)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	0/ 464 (0.0)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	0/ 332 (0.0)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	0/ 368 (0.0)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of severe COVID-19 attributable to a matched variant (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	0/ 94 (0.0)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	0/ 505 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G3.2.5: Anteil an Patient:innen mit entweder COVID-19-bezogener Hospitalisierung oder Tod

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 90)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	2 (0.4)	3 (0.6)
Number of censored subjects, n (%)	546 (99.6)	522 (99.4)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.65 (0.10, 4.01)	
p-value	0.6413	
Relative Risk (95% CI) [3]	0.75 (0.15, 3.85)	
p-value	0.7307	
Odds Ratio (95% CI) [3]	0.74 (0.14, 3.89)	
p-value	0.7212	
Risk Difference (95% CI) [3]	-0.18 (-1.02, 0.65)	
p-value	0.6644	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.63 (0.11, 3.79)	
p-value	0.6179	
Relative Risk (95% CI) [3]	0.64 (0.11, 3.81)	
p-value	0.6226	
Odds Ratio (95% CI) [3]	0.64 (0.11, 3.83)	
p-value	0.6225	
Risk Difference (95% CI) [3]	-0.21 (-1.03, 0.61)	
p-value	0.6212	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	1/ 360 (0.3)	2/ 352 (0.6)			
>= 65	1/ 188 (0.5)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	2/ 274 (0.7)			
Female	2/ 299 (0.7)	1/ 251 (0.4)			
Region					
US	2/ 323 (0.6)	1/ 272 (0.4)			
Europe	0/ 158 (0.0)	2/ 173 (1.2)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	1/ 74 (1.4)	1/ 78 (1.3)			
No	1/ 474 (0.2)	2/ 447 (0.4)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	2/ 524 (0.4)	3/ 498 (0.6)			
AZD7442 use within 12 months prior to randomization					
Yes	1/ 100 (1.0)	0/ 98 (0.0)			
No	1/ 448 (0.2)	3/ 427 (0.7)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	1/ 101 (1.0)			
No	1/ 454 (0.2)	2/ 424 (0.5)			
Solid organ or stem cell transplants					
Yes	1/ 268 (0.4)	2/ 263 (0.8)			
No	1/ 280 (0.4)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	2/ 530 (0.4)	3/ 505 (0.6)			
Taking immunosuppressive medicines					
Yes	2/ 491 (0.4)	2/ 464 (0.4)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	3/ 332 (0.9)			
Abnormal	2/ 184 (1.1)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	1/ 348 (0.3)	3/ 368 (0.8)			
>=30 kg/m2	1/ 198 (0.5)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 90) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	2/ 448 (0.4)	2/ 431 (0.5)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	2/ 525 (0.4)	3/ 505 (0.6)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 180)
Full pre-exposure analysis Set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	3 (0.5)	4 (0.8)
Number of censored subjects, n (%)	545 (99.5)	521 (99.2)
Stratified Analysis AZD3152/AZD3152 vs. Comparator [1]		
Poisson regression (95% CI) [2]	0.71 (0.16, 3.21)	
p-value	0.6520	
Relative Risk (95% CI) [3]	0.79 (0.19, 3.17)	
p-value	0.7345	
Odds Ratio (95% CI) [3]	0.78 (0.19, 3.20)	
p-value	0.7272	
Risk Difference (95% CI) [3]	-0.20 (-1.18, 0.78)	
p-value	0.6925	
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Poisson regression (95% CI) [4]	0.71 (0.16, 3.15)	
p-value	0.6482	
Relative Risk (95% CI) [3]	0.72 (0.16, 3.20)	
p-value	0.6641	
Odds Ratio (95% CI) [3]	0.72 (0.16, 3.22)	
p-value	0.6641	
Risk Difference (95% CI) [3]	-0.21 (-1.18, 0.75)	
p-value	0.6638	

[1] Stratified by randomization stratification factors.
[2] Poisson regression with robust variance, which includes study intervention and the randomization stratification factors as covariates, adjusts for follow-up time and patient-id in REPEAT statement.
[3] Calculated using normal approximation (Wald).
[4] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
Randomization stratification factors for Possion regression: COVID-19 vaccination status within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
Randomization stratification factors for others: COVID-19 vaccination status within six months prior to randomization, severe SARS-CoV-2 infection within six months prior to randomization and AZD7442 use within 12 months prior to randomization.
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 65	1/ 360 (0.3)	3/ 352 (0.9)			
>= 65	2/ 188 (1.1)	1/ 173 (0.6)			
Sex					
Male	1/ 249 (0.4)	3/ 274 (1.1)			
Female	2/ 299 (0.7)	1/ 251 (0.4)			
Region					
US	2/ 323 (0.6)	2/ 272 (0.7)			
Europe	1/ 158 (0.6)	2/ 173 (1.2)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	1/ 74 (1.4)	1/ 78 (1.3)			
No	2/ 474 (0.4)	3/ 447 (0.7)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	3/ 524 (0.6)	4/ 498 (0.8)			
AZD7442 use within 12 months prior to randomization					
Yes	1/ 100 (1.0)	0/ 98 (0.0)			
No	2/ 448 (0.4)	4/ 427 (0.9)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	1/ 101 (1.0)			
No	2/ 454 (0.4)	3/ 424 (0.7)			
Solid organ or stem cell transplants					
Yes	2/ 268 (0.7)	3/ 263 (1.1)			
No	1/ 280 (0.4)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	3/ 530 (0.6)	4/ 505 (0.8)			
Taking immunosuppressive medicines					
Yes	3/ 491 (0.6)	3/ 464 (0.6)			
No	0/ 57 (0.0)	1/ 61 (1.6)			
Electrocardiogram (ECG) interpretation					
Normal	1/ 328 (0.3)	3/ 332 (0.9)			
Abnormal	2/ 184 (1.1)	1/ 171 (0.6)			
Body Mass Index					
<30 kg/m2	1/ 348 (0.3)	4/ 368 (1.1)			
>=30 kg/m2	2/ 198 (1.0)	0/ 151 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Analysis of Incidence of composite of COVID-19-related hospitalization or death (CUTOFF DAY 180) - Subgroup analysis
Full pre-exposure analysis Set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	3/ 448 (0.7)	3/ 431 (0.7)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	3/ 525 (0.6)	4/ 505 (0.8)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

Anhang 4-G3.3: Sicherheit

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	385 (70.3)	353 (67.2)
Number of censored subjects, n (%)	163 (29.7)	172 (32.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.04 (0.96, 1.13)	
p-value	0.2871	
Odds Ratio (95% CI) [1]	1.15 (0.89, 1.49)	
p-value	0.2865	
Risk Difference (95% CI) [1]	3.02 (-2.53, 8.56)	
p-value	0.2863	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.3880
< 65	261/ 360 (72.5)	238/ 352 (67.6)	1.07 (0.97, 1.18)	0.1556	
>= 65	124/ 188 (66.0)	115/ 173 (66.5)	0.99 (0.86, 1.15)	0.9174	
Sex					0.5112
Male	176/ 249 (70.7)	190/ 274 (69.3)	1.02 (0.91, 1.14)	0.7383	
Female	209/ 299 (69.9)	163/ 251 (64.9)	1.08 (0.96, 1.21)	0.2194	
Region					0.9432
US	196/ 323 (60.7)	156/ 272 (57.4)	1.06 (0.92, 1.21)	0.4126	
Europe	133/ 158 (84.2)	134/ 173 (77.5)	1.09 (0.98, 1.21)	0.1205	
Other	56/ 67 (83.6)	63/ 80 (78.8)	1.06 (0.91, 1.24)	0.4533	
COVID-19 vaccination status within six months prior to randomization					0.7422
Yes	58/ 74 (78.4)	60/ 78 (76.9)	1.02 (0.86, 1.21)	0.8295	
No	327/ 474 (69.0)	293/ 447 (65.5)	1.05 (0.96, 1.15)	0.2672	
Prior SARS-CoV-2 infection within six months prior to randomization					0.8413
Yes	18/ 24 (75.0)	20/ 27 (74.1)	1.01 (0.73, 1.40)	0.9396	
No	367/ 524 (70.0)	333/ 498 (66.9)	1.05 (0.96, 1.14)	0.2764	
AZD7442 use within 12 months prior to randomization					0.5418
Yes	71/ 100 (71.0)	70/ 98 (71.4)	0.99 (0.83, 1.19)	0.9469	
No	314/ 448 (70.1)	283/ 427 (66.3)	1.06 (0.97, 1.16)	0.2271	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.4458
Yes	73/ 94 (77.7)	79/ 101 (78.2)	0.99 (0.85, 1.15)	0.9252	
No	312/ 454 (68.7)	274/ 424 (64.6)	1.06 (0.97, 1.17)	0.1990	
Solid organ or stem cell transplants					0.2250
Yes	181/ 268 (67.5)	179/ 263 (68.1)	0.99 (0.88, 1.12)	0.8973	
No	204/ 280 (72.9)	174/ 262 (66.4)	1.10 (0.98, 1.23)	0.1048	
Solid tumor cancer and on active treatment					0.8353
Yes	10/ 18 (55.6)	10/ 20 (50.0)	1.11 (0.61, 2.03)	0.7317	
No	375/ 530 (70.8)	343/ 505 (67.9)	1.04 (0.96, 1.13)	0.3236	
Taking immunosuppressive medicines					0.9995
Yes	342/ 491 (69.7)	309/ 464 (66.6)	1.05 (0.96, 1.14)	0.3114	
No	43/ 57 (75.4)	44/ 61 (72.1)	1.05 (0.84, 1.30)	0.6829	
Electrocardiogram (ECG) interpretation					0.3337
Normal	244/ 328 (74.4)	226/ 332 (68.1)	1.09 (0.99, 1.20)	0.0737	
Abnormal	117/ 184 (63.6)	109/ 171 (63.7)	1.00 (0.85, 1.17)	0.9757	
Body Mass Index					0.4139
<30 kg/m2	250/ 348 (71.8)	247/ 368 (67.1)	1.07 (0.97, 1.18)	0.1705	
>=30 kg/m2	133/ 198 (67.2)	102/ 151 (67.5)	0.99 (0.86, 1.15)	0.9405	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.7453
Yes	77/ 100 (77.0)	71/ 94 (75.5)	1.02 (0.87, 1.19)	0.8103	
No	308/ 448 (68.8)	282/ 431 (65.4)	1.05 (0.96, 1.15)	0.2956	
Moderate or severe secondary Immunodeficiency					0.5779
Yes	14/ 23 (60.9)	10/ 20 (50.0)	1.22 (0.70, 2.10)	0.4811	
No	371/ 525 (70.7)	343/ 505 (67.9)	1.04 (0.96, 1.13)	0.3401	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	354 (64.6)	322 (61.3)
Number of censored subjects, n (%)	194 (35.4)	203 (38.7)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.05 (0.96, 1.15)	
p-value	0.2689	
Odds Ratio (95% CI) [1]	1.15 (0.90, 1.47)	
p-value	0.2682	
Risk Difference (95% CI) [1]	3.27 (-2.51, 9.04)	
p-value	0.2680	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.5642
< 65	235/ 360 (65.3)	214/ 352 (60.8)	1.07 (0.96, 1.20)	0.2163	
>= 65	119/ 188 (63.3)	108/ 173 (62.4)	1.01 (0.87, 1.19)	0.8643	
Sex					0.6062
Male	162/ 249 (65.1)	173/ 274 (63.1)	1.03 (0.91, 1.17)	0.6471	
Female	192/ 299 (64.2)	149/ 251 (59.4)	1.08 (0.95, 1.24)	0.2463	
Region					0.9368
US	177/ 323 (54.8)	140/ 272 (51.5)	1.06 (0.91, 1.24)	0.4194	
Europe	123/ 158 (77.8)	124/ 173 (71.7)	1.09 (0.96, 1.23)	0.1962	
Other	54/ 67 (80.6)	58/ 80 (72.5)	1.11 (0.93, 1.33)	0.2462	
COVID-19 vaccination status within six months prior to randomization					0.6883
Yes	54/ 74 (73.0)	56/ 78 (71.8)	1.02 (0.84, 1.24)	0.8710	
No	300/ 474 (63.3)	266/ 447 (59.5)	1.06 (0.96, 1.18)	0.2395	
Prior SARS-CoV-2 infection within six months prior to randomization					0.9800
Yes	16/ 24 (66.7)	17/ 27 (63.0)	1.06 (0.71, 1.59)	0.7819	
No	338/ 524 (64.5)	305/ 498 (61.2)	1.05 (0.96, 1.16)	0.2819	
AZD7442 use within 12 months prior to randomization					0.3782
Yes	61/ 100 (61.0)	62/ 98 (63.3)	0.96 (0.78, 1.20)	0.7425	
No	293/ 448 (65.4)	260/ 427 (60.9)	1.07 (0.97, 1.19)	0.1677	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.5095
Yes	67/ 94 (71.3)	72/ 101 (71.3)	1.00 (0.84, 1.19)	0.9987	
No	287/ 454 (63.2)	250/ 424 (59.0)	1.07 (0.96, 1.19)	0.1976	
Solid organ or stem cell transplants					0.0883
Yes	163/ 268 (60.8)	165/ 263 (62.7)	0.97 (0.85, 1.11)	0.6495	
No	191/ 280 (68.2)	157/ 262 (59.9)	1.14 (1.00, 1.29)	0.0460	
Solid tumor cancer and on active treatment					0.8570
Yes	10/ 18 (55.6)	10/ 20 (50.0)	1.11 (0.61, 2.03)	0.7317	
No	344/ 530 (64.9)	312/ 505 (61.8)	1.05 (0.96, 1.15)	0.2979	
Taking immunosuppressive medicines					0.8991
Yes	312/ 491 (63.5)	280/ 464 (60.3)	1.05 (0.95, 1.16)	0.3096	
No	42/ 57 (73.7)	42/ 61 (68.9)	1.07 (0.85, 1.35)	0.5620	
Electrocardiogram (ECG) interpretation					0.5025
Normal	223/ 328 (68.0)	207/ 332 (62.3)	1.09 (0.98, 1.22)	0.1291	
Abnormal	107/ 184 (58.2)	98/ 171 (57.3)	1.01 (0.85, 1.21)	0.8725	
Body Mass Index					0.1454
<30 kg/m2	232/ 348 (66.7)	222/ 368 (60.3)	1.11 (0.99, 1.24)	0.0784	
>=30 kg/m2	120/ 198 (60.6)	96/ 151 (63.6)	0.95 (0.81, 1.12)	0.5695	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.6104
Yes	77/ 100 (77.0)	66/ 94 (70.2)	1.10 (0.93, 1.30)	0.2867	
No	277/ 448 (61.8)	256/ 431 (59.4)	1.04 (0.94, 1.16)	0.4608	
Moderate or severe secondary Immunodeficiency					0.5973
Yes	14/ 23 (60.9)	10/ 20 (50.0)	1.22 (0.70, 2.10)	0.4811	
No	340/ 525 (64.8)	312/ 505 (61.8)	1.05 (0.95, 1.15)	0.3219	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	71 (13.0)	63 (12.0)
Number of censored subjects, n (%)	477 (87.0)	462 (88.0)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.08 (0.79, 1.48)	
p-value	0.6359	
Odds Ratio (95% CI) [1]	1.09 (0.76, 1.57)	
p-value	0.6358	
Risk Difference (95% CI) [1]	0.96 (-3.00, 4.91)	
p-value	0.6355	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.1408
< 65	38/ 360 (10.6)	42/ 352 (11.9)	0.88 (0.59, 1.34)	0.5613	
>= 65	33/ 188 (17.6)	21/ 173 (12.1)	1.45 (0.87, 2.40)	0.1536	
Sex					0.6102
Male	34/ 249 (13.7)	37/ 274 (13.5)	1.01 (0.66, 1.56)	0.9598	
Female	37/ 299 (12.4)	26/ 251 (10.4)	1.19 (0.74, 1.92)	0.4609	
Region					0.3157
US	36/ 323 (11.1)	31/ 272 (11.4)	0.98 (0.62, 1.54)	0.9230	
Europe	23/ 158 (14.6)	25/ 173 (14.5)	1.01 (0.60, 1.70)	0.9782	
Other	12/ 67 (17.9)	7/ 80 (8.8)	2.05 (0.85, 4.90)	0.1081	
COVID-19 vaccination status within six months prior to randomization					0.2456
Yes	6/ 74 (8.1)	10/ 78 (12.8)	0.63 (0.24, 1.65)	0.3500	
No	65/ 474 (13.7)	53/ 447 (11.9)	1.16 (0.82, 1.62)	0.4003	
Prior SARS-CoV-2 infection within six months prior to randomization					0.6353
Yes	4/ 24 (16.7)	3/ 27 (11.1)	1.50 (0.37, 6.04)	0.5682	
No	67/ 524 (12.8)	60/ 498 (12.0)	1.06 (0.77, 1.47)	0.7208	
AZD7442 use within 12 months prior to randomization					0.7674
Yes	13/ 100 (13.0)	13/ 98 (13.3)	0.98 (0.48, 2.01)	0.9559	
No	58/ 448 (12.9)	50/ 427 (11.7)	1.11 (0.78, 1.58)	0.5785	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.4593
Yes	10/ 94 (10.6)	13/ 101 (12.9)	0.83 (0.38, 1.79)	0.6299	
No	61/ 454 (13.4)	50/ 424 (11.8)	1.14 (0.80, 1.62)	0.4646	
Solid organ or stem cell transplants					0.6856
Yes	42/ 268 (15.7)	40/ 263 (15.2)	1.03 (0.69, 1.53)	0.8828	
No	29/ 280 (10.4)	23/ 262 (8.8)	1.18 (0.70, 1.99)	0.5336	
Solid tumor cancer and on active treatment					0.3991
Yes	5/ 18 (27.8)	3/ 20 (15.0)	1.85 (0.51, 6.67)	0.3461	
No	66/ 530 (12.5)	60/ 505 (11.9)	1.05 (0.76, 1.45)	0.7787	
Taking immunosuppressive medicines					0.9765
Yes	62/ 491 (12.6)	54/ 464 (11.6)	1.09 (0.77, 1.53)	0.6401	
No	9/ 57 (15.8)	9/ 61 (14.8)	1.07 (0.46, 2.50)	0.8758	
Electrocardiogram (ECG) interpretation					0.7113
Normal	42/ 328 (12.8)	40/ 332 (12.0)	1.06 (0.71, 1.59)	0.7683	
Abnormal	26/ 184 (14.1)	20/ 171 (11.7)	1.21 (0.70, 2.08)	0.4961	
Body Mass Index					0.9111
<30 kg/m2	43/ 348 (12.4)	41/ 368 (11.1)	1.11 (0.74, 1.66)	0.6137	
>=30 kg/m2	28/ 198 (14.1)	20/ 151 (13.2)	1.07 (0.63, 1.82)	0.8098	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.6633
Yes	17/ 100 (17.0)	13/ 94 (13.8)	1.23 (0.63, 2.39)	0.5430	
No	54/ 448 (12.1)	50/ 431 (11.6)	1.04 (0.72, 1.49)	0.8355	
Moderate or severe secondary Immunodeficiency					0.7950
Yes	7/ 23 (30.4)	5/ 20 (25.0)	1.22 (0.46, 3.24)	0.6936	
No	64/ 525 (12.2)	58/ 505 (11.5)	1.06 (0.76, 1.48)	0.7263	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	64 (11.7)	56 (10.7)
Number of censored subjects, n (%)	484 (88.3)	469 (89.3)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.09 (0.78, 1.54)	
p-value	0.5992	
Odds Ratio (95% CI) [1]	1.11 (0.76, 1.62)	
p-value	0.5991	
Risk Difference (95% CI) [1]	1.01 (-2.76, 4.78)	
p-value	0.5986	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.1337
< 65	32/ 360 (8.9)	36/ 352 (10.2)	0.87 (0.55, 1.37)	0.5439	
>= 65	32/ 188 (17.0)	20/ 173 (11.6)	1.47 (0.88, 2.47)	0.1441	
Sex					0.7953
Male	32/ 249 (12.9)	33/ 274 (12.0)	1.07 (0.68, 1.68)	0.7798	
Female	32/ 299 (10.7)	23/ 251 (9.2)	1.17 (0.70, 1.94)	0.5498	
Region					0.4341
US	34/ 323 (10.5)	27/ 272 (9.9)	1.06 (0.66, 1.71)	0.8102	
Europe	19/ 158 (12.0)	22/ 173 (12.7)	0.95 (0.53, 1.68)	0.8488	
Other	11/ 67 (16.4)	7/ 80 (8.8)	1.88 (0.77, 4.57)	0.1659	
COVID-19 vaccination status within six months prior to randomization					0.2124
Yes	5/ 74 (6.8)	9/ 78 (11.5)	0.59 (0.21, 1.67)	0.3160	
No	59/ 474 (12.4)	47/ 447 (10.5)	1.18 (0.83, 1.70)	0.3593	
Prior SARS-CoV-2 infection within six months prior to randomization					0.6500
Yes	4/ 24 (16.7)	3/ 27 (11.1)	1.50 (0.37, 6.04)	0.5682	
No	60/ 524 (11.5)	53/ 498 (10.6)	1.08 (0.76, 1.52)	0.6807	
AZD7442 use within 12 months prior to randomization					0.4215
Yes	10/ 100 (10.0)	12/ 98 (12.2)	0.82 (0.37, 1.80)	0.6161	
No	54/ 448 (12.1)	44/ 427 (10.3)	1.17 (0.80, 1.70)	0.4129	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.4189
Yes	9/ 94 (9.6)	12/ 101 (11.9)	0.81 (0.36, 1.82)	0.6047	
No	55/ 454 (12.1)	44/ 424 (10.4)	1.17 (0.80, 1.70)	0.4169	
Solid organ or stem cell transplants					0.9814
Yes	38/ 268 (14.2)	34/ 263 (12.9)	1.10 (0.71, 1.69)	0.6739	
No	26/ 280 (9.3)	22/ 262 (8.4)	1.11 (0.64, 1.90)	0.7161	
Solid tumor cancer and on active treatment					0.4111
Yes	5/ 18 (27.8)	3/ 20 (15.0)	1.85 (0.51, 6.67)	0.3461	
No	59/ 530 (11.1)	53/ 505 (10.5)	1.06 (0.75, 1.51)	0.7417	
Taking immunosuppressive medicines					0.9526
Yes	56/ 491 (11.4)	48/ 464 (10.3)	1.10 (0.77, 1.59)	0.5993	
No	8/ 57 (14.0)	8/ 61 (13.1)	1.07 (0.43, 2.66)	0.8840	
Electrocardiogram (ECG) interpretation					0.5579
Normal	36/ 328 (11.0)	35/ 332 (10.5)	1.04 (0.67, 1.62)	0.8574	
Abnormal	25/ 184 (13.6)	18/ 171 (10.5)	1.29 (0.73, 2.28)	0.3793	
Body Mass Index					0.4180
<30 kg/m2	41/ 348 (11.8)	35/ 368 (9.5)	1.24 (0.81, 1.90)	0.3253	
>=30 kg/m2	23/ 198 (11.6)	19/ 151 (12.6)	0.92 (0.52, 1.63)	0.7833	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.7903
Yes	14/ 100 (14.0)	11/ 94 (11.7)	1.20 (0.57, 2.50)	0.6339	
No	50/ 448 (11.2)	45/ 431 (10.4)	1.07 (0.73, 1.56)	0.7312	
Moderate or severe secondary Immunodeficiency					0.8151
Yes	7/ 23 (30.4)	5/ 20 (25.0)	1.22 (0.46, 3.24)	0.6936	
No	57/ 525 (10.9)	51/ 505 (10.1)	1.08 (0.75, 1.54)	0.6915	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	67 (12.2)	64 (12.2)
Number of censored subjects, n (%)	481 (87.8)	461 (87.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.00 (0.73, 1.38)	
p-value	0.9857	
Odds Ratio (95% CI) [1]	1.00 (0.70, 1.45)	
p-value	0.9857	
Risk Difference (95% CI) [1]	0.04 (-3.88, 3.95)	
p-value	0.9857	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.0856
< 65	37/ 360 (10.3)	45/ 352 (12.8)	0.80 (0.53, 1.21)	0.2962	
>= 65	30/ 188 (16.0)	19/ 173 (11.0)	1.45 (0.85, 2.48)	0.1721	
Sex					0.3148
Male	33/ 249 (13.3)	41/ 274 (15.0)	0.89 (0.58, 1.35)	0.5756	
Female	34/ 299 (11.4)	23/ 251 (9.2)	1.24 (0.75, 2.05)	0.3992	
Region					0.7082
US	33/ 323 (10.2)	26/ 272 (9.6)	1.07 (0.66, 1.74)	0.7892	
Europe	22/ 158 (13.9)	27/ 173 (15.6)	0.89 (0.53, 1.50)	0.6671	
Other	12/ 67 (17.9)	11/ 80 (13.8)	1.30 (0.61, 2.76)	0.4903	
COVID-19 vaccination status within six months prior to randomization					0.4536
Yes	6/ 74 (8.1)	9/ 78 (11.5)	0.70 (0.26, 1.88)	0.4817	
No	61/ 474 (12.9)	55/ 447 (12.3)	1.05 (0.74, 1.47)	0.7963	
Prior SARS-CoV-2 infection within six months prior to randomization					0.8778
Yes	3/ 24 (12.5)	3/ 27 (11.1)	1.13 (0.25, 5.06)	0.8779	
No	64/ 524 (12.2)	61/ 498 (12.2)	1.00 (0.72, 1.38)	0.9863	
AZD7442 use within 12 months prior to randomization					0.7576
Yes	11/ 100 (11.0)	12/ 98 (12.2)	0.90 (0.42, 1.94)	0.7847	
No	56/ 448 (12.5)	52/ 427 (12.2)	1.03 (0.72, 1.46)	0.8849	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.5715
Yes	9/ 94 (9.6)	12/ 101 (11.9)	0.81 (0.36, 1.82)	0.6047	
No	58/ 454 (12.8)	52/ 424 (12.3)	1.04 (0.73, 1.48)	0.8192	
Solid organ or stem cell transplants					0.7129
Yes	37/ 268 (13.8)	38/ 263 (14.4)	0.96 (0.63, 1.45)	0.8316	
No	30/ 280 (10.7)	26/ 262 (9.9)	1.08 (0.66, 1.78)	0.7626	
Solid tumor cancer and on active treatment					0.3523
Yes	6/ 18 (33.3)	4/ 20 (20.0)	1.67 (0.56, 4.97)	0.3598	
No	61/ 530 (11.5)	60/ 505 (11.9)	0.97 (0.69, 1.35)	0.8524	
Taking immunosuppressive medicines					0.8791
Yes	58/ 491 (11.8)	55/ 464 (11.9)	1.00 (0.70, 1.41)	0.9844	
No	9/ 57 (15.8)	9/ 61 (14.8)	1.07 (0.46, 2.50)	0.8758	
Electrocardiogram (ECG) interpretation					0.6424
Normal	39/ 328 (11.9)	40/ 332 (12.0)	0.99 (0.65, 1.49)	0.9502	
Abnormal	25/ 184 (13.6)	20/ 171 (11.7)	1.16 (0.67, 2.01)	0.5932	
Body Mass Index					0.5481
<30 kg/m2	37/ 348 (10.6)	42/ 368 (11.4)	0.93 (0.61, 1.41)	0.7390	
>=30 kg/m2	30/ 198 (15.2)	20/ 151 (13.2)	1.14 (0.68, 1.93)	0.6154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.6535
Yes	17/ 100 (17.0)	14/ 94 (14.9)	1.14 (0.60, 2.18)	0.6895	
No	50/ 448 (11.2)	50/ 431 (11.6)	0.96 (0.67, 1.39)	0.8372	
Moderate or severe secondary Immunodeficiency					0.8205
Yes	4/ 23 (17.4)	4/ 20 (20.0)	0.87 (0.25, 3.03)	0.8265	
No	63/ 525 (12.0)	60/ 505 (11.9)	1.01 (0.72, 1.41)	0.9531	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	61 (11.1)	57 (10.9)
Number of censored subjects, n (%)	487 (88.9)	468 (89.1)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.03 (0.73, 1.44)	
p-value	0.8859	
Odds Ratio (95% CI) [1]	1.03 (0.70, 1.51)	
p-value	0.8859	
Risk Difference (95% CI) [1]	0.27 (-3.47, 4.02)	
p-value	0.8858	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					0.0888
< 65	32/ 360 (8.9)	39/ 352 (11.1)	0.80 (0.51, 1.25)	0.3306	
>= 65	29/ 188 (15.4)	18/ 173 (10.4)	1.48 (0.85, 2.57)	0.1611	
Sex					0.5070
Male	31/ 249 (12.4)	36/ 274 (13.1)	0.95 (0.61, 1.48)	0.8139	
Female	30/ 299 (10.0)	21/ 251 (8.4)	1.20 (0.70, 2.04)	0.5031	
Region					0.6844
US	32/ 323 (9.9)	23/ 272 (8.5)	1.17 (0.70, 1.95)	0.5435	
Europe	18/ 158 (11.4)	23/ 173 (13.3)	0.86 (0.48, 1.53)	0.6004	
Other	11/ 67 (16.4)	11/ 80 (13.8)	1.19 (0.55, 2.58)	0.6518	
COVID-19 vaccination status within six months prior to randomization					0.5938
Yes	6/ 74 (8.1)	8/ 78 (10.3)	0.79 (0.29, 2.17)	0.6482	
No	55/ 474 (11.6)	49/ 447 (11.0)	1.06 (0.74, 1.52)	0.7586	
Prior SARS-CoV-2 infection within six months prior to randomization					0.9017
Yes	3/ 24 (12.5)	3/ 27 (11.1)	1.13 (0.25, 5.06)	0.8779	
No	58/ 524 (11.1)	54/ 498 (10.8)	1.02 (0.72, 1.45)	0.9082	
AZD7442 use within 12 months prior to randomization					0.5271
Yes	9/ 100 (9.0)	11/ 98 (11.2)	0.80 (0.35, 1.85)	0.6045	
No	52/ 448 (11.6)	46/ 427 (10.8)	1.08 (0.74, 1.57)	0.6958	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.6949
Yes	9/ 94 (9.6)	11/ 101 (10.9)	0.88 (0.38, 2.03)	0.7623	
No	52/ 454 (11.5)	46/ 424 (10.8)	1.06 (0.73, 1.53)	0.7762	
Solid organ or stem cell transplants					0.9289
Yes	34/ 268 (12.7)	32/ 263 (12.2)	1.04 (0.66, 1.64)	0.8561	
No	27/ 280 (9.6)	25/ 262 (9.5)	1.01 (0.60, 1.70)	0.9682	
Solid tumor cancer and on active treatment					0.3736
Yes	6/ 18 (33.3)	4/ 20 (20.0)	1.67 (0.56, 4.97)	0.3598	
No	55/ 530 (10.4)	53/ 505 (10.5)	0.99 (0.69, 1.41)	0.9506	
Taking immunosuppressive medicines					0.9270
Yes	53/ 491 (10.8)	49/ 464 (10.6)	1.02 (0.71, 1.48)	0.9069	
No	8/ 57 (14.0)	8/ 61 (13.1)	1.07 (0.43, 2.66)	0.8840	
Electrocardiogram (ECG) interpretation					0.4148
Normal	33/ 328 (10.1)	35/ 332 (10.5)	0.95 (0.61, 1.50)	0.8389	
Abnormal	25/ 184 (13.6)	18/ 171 (10.5)	1.29 (0.73, 2.28)	0.3793	
Body Mass Index					0.8848
<30 kg/m2	36/ 348 (10.3)	36/ 368 (9.8)	1.06 (0.68, 1.64)	0.8026	
>=30 kg/m2	25/ 198 (12.6)	19/ 151 (12.6)	1.00 (0.57, 1.75)	0.9903	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.8335
Yes	14/ 100 (14.0)	12/ 94 (12.8)	1.10 (0.53, 2.25)	0.8011	
No	47/ 448 (10.5)	45/ 431 (10.4)	1.00 (0.68, 1.48)	0.9806	
Moderate or severe secondary Immunodeficiency					0.7932
Yes	4/ 23 (17.4)	4/ 20 (20.0)	0.87 (0.25, 3.03)	0.8265	
No	57/ 525 (10.9)	53/ 505 (10.5)	1.03 (0.73, 1.47)	0.8508	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AE - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	373 (68.1)	343 (65.3)
Number of censored subjects, n (%)	175 (31.9)	182 (34.7)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.04 (0.96, 1.13)	
p-value	0.3430	
Odds Ratio (95% CI) [1]	1.13 (0.88, 1.46)	
p-value	0.3424	
Risk Difference (95% CI) [1]	2.73 (-2.91, 8.37)	
p-value	0.3424	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.3135
< 65	254/ 360 (70.6)	231/ 352 (65.6)	1.08 (0.97, 1.19)	0.1591	
>= 65	119/ 188 (63.3)	112/ 173 (64.7)	0.98 (0.84, 1.14)	0.7754	
Sex					0.7272
Male	171/ 249 (68.7)	183/ 274 (66.8)	1.03 (0.91, 1.16)	0.6446	
Female	202/ 299 (67.6)	160/ 251 (63.7)	1.06 (0.94, 1.20)	0.3504	
Region					0.9207
US	187/ 323 (57.9)	150/ 272 (55.1)	1.05 (0.91, 1.21)	0.5018	
Europe	130/ 158 (82.3)	132/ 173 (76.3)	1.08 (0.97, 1.20)	0.1796	
Other	56/ 67 (83.6)	61/ 80 (76.3)	1.10 (0.93, 1.29)	0.2664	
COVID-19 vaccination status within six months prior to randomization					0.7700
Yes	57/ 74 (77.0)	59/ 78 (75.6)	1.02 (0.85, 1.22)	0.8407	
No	316/ 474 (66.7)	284/ 447 (63.5)	1.05 (0.95, 1.15)	0.3197	
Prior SARS-CoV-2 infection within six months prior to randomization					0.8545
Yes	18/ 24 (75.0)	20/ 27 (74.1)	1.01 (0.73, 1.40)	0.9396	
No	355/ 524 (67.7)	323/ 498 (64.9)	1.04 (0.96, 1.14)	0.3295	
AZD7442 use within 12 months prior to randomization					0.5871
Yes	69/ 100 (69.0)	68/ 98 (69.4)	0.99 (0.83, 1.20)	0.9529	
No	304/ 448 (67.9)	275/ 427 (64.4)	1.05 (0.96, 1.16)	0.2813	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.4711
Yes	72/ 94 (76.6)	78/ 101 (77.2)	0.99 (0.85, 1.16)	0.9167	
No	301/ 454 (66.3)	265/ 424 (62.5)	1.06 (0.96, 1.17)	0.2411	
Solid organ or stem cell transplants					0.6702
Yes	177/ 268 (66.0)	170/ 263 (64.6)	1.02 (0.90, 1.16)	0.7336	
No	196/ 280 (70.0)	173/ 262 (66.0)	1.06 (0.94, 1.19)	0.3234	
Solid tumor cancer and on active treatment					0.6256
Yes	7/ 18 (38.9)	9/ 20 (45.0)	0.86 (0.41, 1.84)	0.7048	
No	366/ 530 (69.1)	334/ 505 (66.1)	1.04 (0.96, 1.14)	0.3167	
Taking immunosuppressive medicines					0.9859
Yes	332/ 491 (67.6)	301/ 464 (64.9)	1.04 (0.95, 1.14)	0.3703	
No	41/ 57 (71.9)	42/ 61 (68.9)	1.04 (0.83, 1.32)	0.7143	
Electrocardiogram (ECG) interpretation					0.3162
Normal	238/ 328 (72.6)	220/ 332 (66.3)	1.10 (0.99, 1.21)	0.0799	
Abnormal	112/ 184 (60.9)	105/ 171 (61.4)	0.99 (0.84, 1.17)	0.9178	
Body Mass Index					0.5332
<30 kg/m2	241/ 348 (69.3)	240/ 368 (65.2)	1.06 (0.96, 1.18)	0.2501	
>=30 kg/m2	130/ 198 (65.7)	99/ 151 (65.6)	1.00 (0.86, 1.17)	0.9854	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AE - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.5502
Yes	74/ 100 (74.0)	70/ 94 (74.5)	0.99 (0.84, 1.17)	0.9406	
No	299/ 448 (66.7)	273/ 431 (63.3)	1.05 (0.96, 1.16)	0.2913	
Moderate or severe secondary Immunodeficiency					0.3466
Yes	13/ 23 (56.5)	8/ 20 (40.0)	1.41 (0.74, 2.69)	0.2938	
No	360/ 525 (68.6)	335/ 505 (66.3)	1.03 (0.95, 1.13)	0.4445	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to discontinuation of study treatment - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	4 (0.8)
Number of censored subjects, n (%)	548 (100.0)	521 (99.2)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.11 (0.01, 1.97)	
p-value	0.1326	
Odds Ratio (95% CI) [1]	0.11 (0.01, 1.97)	
p-value	0.1319	
Risk Difference (95% CI) [1]	-0.76 (-1.51, -0.02)	
p-value	0.0447	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to discontinuation of study treatment - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	0/ 360 (0.0)	2/ 352 (0.6)		
>= 65	0/ 188 (0.0)	2/ 173 (1.2)		
Sex				
Male	0/ 249 (0.0)	3/ 274 (1.1)		
Female	0/ 299 (0.0)	1/ 251 (0.4)		
Region				
US	0/ 323 (0.0)	1/ 272 (0.4)		
Europe	0/ 158 (0.0)	3/ 173 (1.7)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	1/ 78 (1.3)		
No	0/ 474 (0.0)	3/ 447 (0.7)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	0/ 524 (0.0)	4/ 498 (0.8)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	1/ 98 (1.0)		
No	0/ 448 (0.0)	3/ 427 (0.7)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	0/ 454 (0.0)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	0/ 268 (0.0)	0/ 263 (0.0)		
No	0/ 280 (0.0)	4/ 262 (1.5)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	0/ 530 (0.0)	4/ 505 (0.8)		
Taking immunosuppressive medicines				
Yes	0/ 491 (0.0)	3/ 464 (0.6)		
No	0/ 57 (0.0)	1/ 61 (1.6)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	3/ 332 (0.9)		
Abnormal	0/ 184 (0.0)	1/ 171 (0.6)		
Body Mass Index				
<30 kg/m2	0/ 348 (0.0)	3/ 368 (0.8)		
>=30 kg/m2	0/ 198 (0.0)	1/ 151 (0.7)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to discontinuation of study treatment - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	2/ 94 (2.1)			
No	0/ 448 (0.0)	2/ 431 (0.5)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	4/ 505 (0.8)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to death - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	3 (0.5)	3 (0.6)
Number of censored subjects, n (%)	545 (99.5)	522 (99.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.96 (0.19, 4.73)	
p-value	0.9580	
Odds Ratio (95% CI) [1]	0.96 (0.19, 4.77)	
p-value	0.9580	
Risk Difference (95% CI) [1]	-0.02 (-0.92, 0.87)	
p-value	0.9580	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to death - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	1/ 188 (0.5)	2/ 173 (1.2)		
Sex				
Male	2/ 249 (0.8)	3/ 274 (1.1)		
Female	1/ 299 (0.3)	0/ 251 (0.0)		
Region				
US	2/ 323 (0.6)	0/ 272 (0.0)		
Europe	1/ 158 (0.6)	2/ 173 (1.2)		
Other	0/ 67 (0.0)	1/ 80 (1.3)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	1/ 78 (1.3)		
No	3/ 474 (0.6)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	3/ 524 (0.6)	3/ 498 (0.6)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	3/ 448 (0.7)	3/ 427 (0.7)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	3/ 454 (0.7)	2/ 424 (0.5)		
Solid organ or stem cell transplants				
Yes	1/ 268 (0.4)	1/ 263 (0.4)		
No	2/ 280 (0.7)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	2/ 18 (11.1)	0/ 20 (0.0)		
No	1/ 530 (0.2)	3/ 505 (0.6)		
Taking immunosuppressive medicines				
Yes	3/ 491 (0.6)	2/ 464 (0.4)		
No	0/ 57 (0.0)	1/ 61 (1.6)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	1/ 332 (0.3)		
Abnormal	2/ 184 (1.1)	1/ 171 (0.6)		
Body Mass Index				
<30 kg/m2	2/ 348 (0.6)	3/ 368 (0.8)		
>=30 kg/m2	1/ 198 (0.5)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to death - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	1/ 100 (1.0)	3/ 94 (3.2)			
No	2/ 448 (0.4)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	3/ 525 (0.6)	3/ 505 (0.6)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	4 (0.8)
Number of censored subjects, n (%)	543 (99.1)	521 (99.2)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.20 (0.32, 4.44)	
p-value	0.7873	
Odds Ratio (95% CI) [1]	1.20 (0.32, 4.49)	
p-value	0.7873	
Risk Difference (95% CI) [1]	0.15 (-0.94, 1.24)	
p-value	0.7866	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	3/ 173 (1.7)		
Sex				
Male	3/ 249 (1.2)	2/ 274 (0.7)		
Female	2/ 299 (0.7)	2/ 251 (0.8)		
Region				
US	3/ 323 (0.9)	2/ 272 (0.7)		
Europe	1/ 158 (0.6)	2/ 173 (1.2)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	5/ 474 (1.1)	4/ 447 (0.9)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	1/ 27 (3.7)		
No	4/ 524 (0.8)	3/ 498 (0.6)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	4/ 427 (0.9)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	1/ 101 (1.0)		
No	4/ 454 (0.9)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	5/ 268 (1.9)	1/ 263 (0.4)		
No	0/ 280 (0.0)	3/ 262 (1.1)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	1/ 20 (5.0)		
No	5/ 530 (0.9)	3/ 505 (0.6)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	4/ 464 (0.9)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	4/ 332 (1.2)		
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	5/ 348 (1.4)	3/ 368 (0.8)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	2/ 94 (2.1)			
No	5/ 448 (1.1)	2/ 431 (0.5)			
Moderate or severe secondary Immunodeficiency					
Yes	2/ 23 (8.7)	0/ 20 (0.0)			
No	3/ 525 (0.6)	4/ 505 (0.8)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	3 (0.6)
Number of censored subjects, n (%)	543 (99.1)	522 (99.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.60 (0.38, 6.65)	
p-value	0.5202	
Odds Ratio (95% CI) [1]	1.60 (0.38, 6.74)	
p-value	0.5201	
Risk Difference (95% CI) [1]	0.34 (-0.68, 1.37)	
p-value	0.5142	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	2/ 173 (1.2)		
Sex				
Male	3/ 249 (1.2)	2/ 274 (0.7)		
Female	2/ 299 (0.7)	1/ 251 (0.4)		
Region				
US	3/ 323 (0.9)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	2/ 173 (1.2)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	5/ 474 (1.1)	3/ 447 (0.7)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	0/ 27 (0.0)		
No	4/ 524 (0.8)	3/ 498 (0.6)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	3/ 427 (0.7)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	0/ 101 (0.0)		
No	4/ 454 (0.9)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	5/ 268 (1.9)	1/ 263 (0.4)		
No	0/ 280 (0.0)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	5/ 530 (0.9)	3/ 505 (0.6)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	3/ 464 (0.6)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	3/ 332 (0.9)		
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	5/ 348 (1.4)	2/ 368 (0.5)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	2/ 94 (2.1)			
No	5/ 448 (1.1)	1/ 431 (0.2)			
Moderate or severe secondary Immunodeficiency					
Yes	2/ 23 (8.7)	0/ 20 (0.0)			
No	3/ 525 (0.6)	3/ 505 (0.6)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	4 (0.7)	2 (0.4)
Number of censored subjects, n (%)	544 (99.3)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.92 (0.35, 10.42)	
p-value	0.4516	
Odds Ratio (95% CI) [1]	1.92 (0.35, 10.54)	
p-value	0.4514	
Risk Difference (95% CI) [1]	0.35 (-0.54, 1.24)	
p-value	0.4403	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	1/ 360 (0.3)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	1/ 173 (0.6)		
Sex				
Male	2/ 249 (0.8)	1/ 274 (0.4)		
Female	2/ 299 (0.7)	1/ 251 (0.4)		
Region				
US	2/ 323 (0.6)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	1/ 173 (0.6)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	4/ 474 (0.8)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	0/ 27 (0.0)		
No	3/ 524 (0.6)	2/ 498 (0.4)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	4/ 448 (0.9)	2/ 427 (0.5)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	0/ 101 (0.0)		
No	3/ 454 (0.7)	2/ 424 (0.5)		
Solid organ or stem cell transplants				
Yes	4/ 268 (1.5)	1/ 263 (0.4)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	4/ 530 (0.8)	2/ 505 (0.4)		
Taking immunosuppressive medicines				
Yes	4/ 491 (0.8)	2/ 464 (0.4)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	2/ 332 (0.6)		
Abnormal	3/ 184 (1.6)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	4/ 348 (1.1)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	4/ 448 (0.9)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	2/ 525 (0.4)	2/ 505 (0.4)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	2 (0.4)
Number of censored subjects, n (%)	547 (99.8)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.48 (0.04, 5.27)	
p-value	0.5474	
Odds Ratio (95% CI) [1]	0.48 (0.04, 5.29)	
p-value	0.5473	
Risk Difference (95% CI) [1]	-0.20 (-0.84, 0.44)	
p-value	0.5412	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	1/ 360 (0.3)	0/ 352 (0.0)		
>= 65	0/ 188 (0.0)	2/ 173 (1.2)		
Sex				
Male	1/ 249 (0.4)	1/ 274 (0.4)		
Female	0/ 299 (0.0)	1/ 251 (0.4)		
Region				
US	1/ 323 (0.3)	1/ 272 (0.4)		
Europe	0/ 158 (0.0)	1/ 173 (0.6)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	1/ 474 (0.2)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	1/ 27 (3.7)		
No	1/ 524 (0.2)	1/ 498 (0.2)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	1/ 448 (0.2)	2/ 427 (0.5)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	1/ 454 (0.2)	1/ 424 (0.2)		
Solid organ or stem cell transplants				
Yes	1/ 268 (0.4)	0/ 263 (0.0)		
No	0/ 280 (0.0)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	1/ 20 (5.0)		
No	1/ 530 (0.2)	1/ 505 (0.2)		
Taking immunosuppressive medicines				
Yes	1/ 491 (0.2)	2/ 464 (0.4)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	2/ 332 (0.6)		
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	1/ 348 (0.3)	2/ 368 (0.5)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	1/ 448 (0.2)	1/ 431 (0.2)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	2/ 505 (0.4)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	3 (0.6)
Number of censored subjects, n (%)	543 (99.1)	522 (99.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.60 (0.38, 6.65)	
p-value	0.5202	
Odds Ratio (95% CI) [1]	1.60 (0.38, 6.74)	
p-value	0.5201	
Risk Difference (95% CI) [1]	0.34 (-0.68, 1.37)	
p-value	0.5142	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	2/ 173 (1.2)		
Sex				
Male	3/ 249 (1.2)	1/ 274 (0.4)		
Female	2/ 299 (0.7)	2/ 251 (0.8)		
Region				
US	3/ 323 (0.9)	2/ 272 (0.7)		
Europe	1/ 158 (0.6)	1/ 173 (0.6)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	5/ 474 (1.1)	3/ 447 (0.7)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	1/ 27 (3.7)		
No	4/ 524 (0.8)	2/ 498 (0.4)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	3/ 427 (0.7)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	1/ 101 (1.0)		
No	4/ 454 (0.9)	2/ 424 (0.5)		
Solid organ or stem cell transplants				
Yes	5/ 268 (1.9)	1/ 263 (0.4)		
No	0/ 280 (0.0)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	1/ 20 (5.0)		
No	5/ 530 (0.9)	2/ 505 (0.4)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	3/ 464 (0.6)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	3/ 332 (0.9)		
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	5/ 348 (1.4)	2/ 368 (0.5)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	5/ 448 (1.1)	2/ 431 (0.5)			
Moderate or severe secondary Immunodeficiency					
Yes	2/ 23 (8.7)	0/ 20 (0.0)			
No	3/ 525 (0.6)	3/ 505 (0.6)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	2 (0.4)
Number of censored subjects, n (%)	543 (99.1)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	2.40 (0.47, 12.29)	
p-value	0.2952	
Odds Ratio (95% CI) [1]	2.41 (0.47, 12.47)	
p-value	0.2949	
Risk Difference (95% CI) [1]	0.53 (-0.42, 1.49)	
p-value	0.2752	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	2/ 360 (0.6)	1/ 352 (0.3)			
>= 65	3/ 188 (1.6)	1/ 173 (0.6)			
Sex					
Male	3/ 249 (1.2)	1/ 274 (0.4)			
Female	2/ 299 (0.7)	1/ 251 (0.4)			
Region					
US	3/ 323 (0.9)	1/ 272 (0.4)			
Europe	1/ 158 (0.6)	1/ 173 (0.6)			
Other	1/ 67 (1.5)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	5/ 474 (1.1)	2/ 447 (0.4)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	1/ 24 (4.2)	0/ 27 (0.0)			
No	4/ 524 (0.8)	2/ 498 (0.4)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	5/ 448 (1.1)	2/ 427 (0.5)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	0/ 101 (0.0)			
No	4/ 454 (0.9)	2/ 424 (0.5)			
Solid organ or stem cell transplants					
Yes	5/ 268 (1.9)	1/ 263 (0.4)			
No	0/ 280 (0.0)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	5/ 530 (0.9)	2/ 505 (0.4)			
Taking immunosuppressive medicines					
Yes	5/ 491 (1.0)	2/ 464 (0.4)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	1/ 328 (0.3)	2/ 332 (0.6)			
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	5/ 348 (1.4)	1/ 368 (0.3)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	5/ 448 (1.1)	1/ 431 (0.2)			
Moderate or severe secondary Immunodeficiency					
Yes	2/ 23 (8.7)	0/ 20 (0.0)			
No	3/ 525 (0.6)	2/ 505 (0.4)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	4 (0.7)	2 (0.4)
Number of censored subjects, n (%)	544 (99.3)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.92 (0.35, 10.42)	
p-value	0.4516	
Odds Ratio (95% CI) [1]	1.92 (0.35, 10.54)	
p-value	0.4514	
Risk Difference (95% CI) [1]	0.35 (-0.54, 1.24)	
p-value	0.4403	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	1/ 360 (0.3)	1/ 352 (0.3)			
>= 65	3/ 188 (1.6)	1/ 173 (0.6)			
Sex					
Male	2/ 249 (0.8)	1/ 274 (0.4)			
Female	2/ 299 (0.7)	1/ 251 (0.4)			
Region					
US	2/ 323 (0.6)	1/ 272 (0.4)			
Europe	1/ 158 (0.6)	1/ 173 (0.6)			
Other	1/ 67 (1.5)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	4/ 474 (0.8)	2/ 447 (0.4)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	1/ 24 (4.2)	0/ 27 (0.0)			
No	3/ 524 (0.6)	2/ 498 (0.4)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	4/ 448 (0.9)	2/ 427 (0.5)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	0/ 101 (0.0)			
No	3/ 454 (0.7)	2/ 424 (0.5)			
Solid organ or stem cell transplants					
Yes	4/ 268 (1.5)	1/ 263 (0.4)			
No	0/ 280 (0.0)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	4/ 530 (0.8)	2/ 505 (0.4)			
Taking immunosuppressive medicines					
Yes	4/ 491 (0.8)	2/ 464 (0.4)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	1/ 328 (0.3)	2/ 332 (0.6)			
Abnormal	3/ 184 (1.6)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	4/ 348 (1.1)	1/ 368 (0.3)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	4/ 448 (0.9)	1/ 431 (0.2)			
Moderate or severe secondary Immunodeficiency					
Yes	2/ 23 (8.7)	0/ 20 (0.0)			
No	2/ 525 (0.4)	2/ 505 (0.4)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Number of censored subjects, n (%)	547 (99.8)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.96 (0.06, 15.28)	
p-value	0.9758	
Odds Ratio (95% CI) [1]	0.96 (0.06, 15.35)	
p-value	0.9758	
Risk Difference (95% CI) [1]	-0.01 (-0.52, 0.51)	
p-value	0.9758	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	1/ 360 (0.3)	0/ 352 (0.0)		
>= 65	0/ 188 (0.0)	1/ 173 (0.6)		
Sex				
Male	1/ 249 (0.4)	0/ 274 (0.0)		
Female	0/ 299 (0.0)	1/ 251 (0.4)		
Region				
US	1/ 323 (0.3)	1/ 272 (0.4)		
Europe	0/ 158 (0.0)	0/ 173 (0.0)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	1/ 474 (0.2)	1/ 447 (0.2)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	1/ 27 (3.7)		
No	1/ 524 (0.2)	0/ 498 (0.0)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	1/ 448 (0.2)	1/ 427 (0.2)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	1/ 454 (0.2)	0/ 424 (0.0)		
Solid organ or stem cell transplants				
Yes	1/ 268 (0.4)	0/ 263 (0.0)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	1/ 20 (5.0)		
No	1/ 530 (0.2)	0/ 505 (0.0)		
Taking immunosuppressive medicines				
Yes	1/ 491 (0.2)	1/ 464 (0.2)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	1/ 332 (0.3)		
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	1/ 348 (0.3)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Cardiovascular and thrombotic events - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	0/ 94 (0.0)		
No	1/ 448 (0.2)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	0/ 23 (0.0)	0/ 20 (0.0)		
No	1/ 525 (0.2)	1/ 505 (0.2)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.32 (0.01, 7.82)	
p-value	0.4843	
Odds Ratio (95% CI) [1]	0.32 (0.01, 7.84)	
p-value	0.4841	
Risk Difference (95% CI) [1]	-0.19 (-0.56, 0.18)	
p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	1/ 447 (0.2)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	1/ 424 (0.2)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	1/ 464 (0.2)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	1/ 505 (0.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.32 (0.01, 7.82)	
p-value	0.4843	
Odds Ratio (95% CI) [1]	0.32 (0.01, 7.84)	
p-value	0.4841	
Risk Difference (95% CI) [1]	-0.19 (-0.56, 0.18)	
p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	1/ 447 (0.2)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	1/ 424 (0.2)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	1/ 464 (0.2)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	1/ 505 (0.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	548 (100.0)	525 (100.0)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	0/ 173 (0.0)			
Sex					
Male	0/ 249 (0.0)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	0/ 427 (0.0)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	0/ 262 (0.0)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	0/ 464 (0.0)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	0/ 332 (0.0)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	0/ 368 (0.0)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	0/ 94 (0.0)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	0/ 505 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.32 (0.01, 7.82)	
p-value	0.4843	
Odds Ratio (95% CI) [1]	0.32 (0.01, 7.84)	
p-value	0.4841	
Risk Difference (95% CI) [1]	-0.19 (-0.56, 0.18)	
p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	1/ 173 (0.6)			
Sex					
Male	0/ 249 (0.0)	1/ 274 (0.4)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	1/ 173 (0.6)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	1/ 447 (0.2)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	1/ 498 (0.2)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	1/ 424 (0.2)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	1/ 505 (0.2)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	1/ 464 (0.2)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	0/ 448 (0.0)	0/ 431 (0.0)		
Moderate or severe secondary Immunodeficiency				
Yes	0/ 23 (0.0)	0/ 20 (0.0)		
No	0/ 525 (0.0)	1/ 505 (0.2)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	407 (74.3)	366 (69.7)
Number of censored subjects, n (%)	141 (25.7)	159 (30.3)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.07 (0.99, 1.15)	
p-value	0.0975	
Odds Ratio (95% CI) [1]	1.25 (0.96, 1.64)	
p-value	0.0968	
Risk Difference (95% CI) [1]	4.56 (-0.81, 9.93)	
p-value	0.0964	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.4278
< 65	274/ 360 (76.1)	246/ 352 (69.9)	1.09 (1.00, 1.19)	0.0624	
>= 65	133/ 188 (70.7)	120/ 173 (69.4)	1.02 (0.89, 1.17)	0.7750	
Sex					0.4910
Male	184/ 249 (73.9)	195/ 274 (71.2)	1.04 (0.93, 1.15)	0.4847	
Female	223/ 299 (74.6)	171/ 251 (68.1)	1.09 (0.98, 1.22)	0.0986	
Region					0.8756
US	213/ 323 (65.9)	168/ 272 (61.8)	1.07 (0.95, 1.21)	0.2928	
Europe	137/ 158 (86.7)	135/ 173 (78.0)	1.11 (1.01, 1.23)	0.0386	
Other	57/ 67 (85.1)	63/ 80 (78.8)	1.08 (0.93, 1.26)	0.3183	
COVID-19 vaccination status within six months prior to randomization					0.4150
Yes	60/ 74 (81.1)	63/ 78 (80.8)	1.00 (0.86, 1.17)	0.9610	
No	347/ 474 (73.2)	303/ 447 (67.8)	1.08 (0.99, 1.17)	0.0725	
Prior SARS-CoV-2 infection within six months prior to randomization					0.6752
Yes	21/ 24 (87.5)	21/ 27 (77.8)	1.13 (0.87, 1.45)	0.3597	
No	386/ 524 (73.7)	345/ 498 (69.3)	1.06 (0.98, 1.15)	0.1216	
AZD7442 use within 12 months prior to randomization					0.4090
Yes	78/ 100 (78.0)	76/ 98 (77.6)	1.01 (0.87, 1.17)	0.9394	
No	329/ 448 (73.4)	290/ 427 (67.9)	1.08 (0.99, 1.18)	0.0740	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.4795
Yes	78/ 94 (83.0)	82/ 101 (81.2)	1.02 (0.90, 1.17)	0.7444	
No	329/ 454 (72.5)	284/ 424 (67.0)	1.08 (0.99, 1.18)	0.0783	
Solid organ or stem cell transplants					0.1539
Yes	192/ 268 (71.6)	187/ 263 (71.1)	1.01 (0.90, 1.12)	0.8907	
No	215/ 280 (76.8)	179/ 262 (68.3)	1.12 (1.01, 1.25)	0.0287	
Solid tumor cancer and on active treatment					0.4098
Yes	12/ 18 (66.7)	10/ 20 (50.0)	1.33 (0.77, 2.30)	0.3023	
No	395/ 530 (74.5)	356/ 505 (70.5)	1.06 (0.98, 1.14)	0.1472	
Taking immunosuppressive medicines					0.6161
Yes	360/ 491 (73.3)	321/ 464 (69.2)	1.06 (0.98, 1.15)	0.1589	
No	47/ 57 (82.5)	45/ 61 (73.8)	1.12 (0.92, 1.35)	0.2550	
Electrocardiogram (ECG) interpretation					0.8014
Normal	254/ 328 (77.4)	235/ 332 (70.8)	1.09 (1.00, 1.20)	0.0516	
Abnormal	129/ 184 (70.1)	112/ 171 (65.5)	1.07 (0.93, 1.24)	0.3544	
Body Mass Index					0.6303
<30 kg/m2	261/ 348 (75.0)	256/ 368 (69.6)	1.08 (0.98, 1.18)	0.1045	
>=30 kg/m2	144/ 198 (72.7)	106/ 151 (70.2)	1.04 (0.91, 1.19)	0.6059	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.6118
Yes	81/ 100 (81.0)	74/ 94 (78.7)	1.03 (0.89, 1.19)	0.6932	
No	326/ 448 (72.8)	292/ 431 (67.7)	1.07 (0.99, 1.17)	0.1047	
Moderate or severe secondary Immunodeficiency					0.7066
Yes	16/ 23 (69.6)	12/ 20 (60.0)	1.16 (0.74, 1.82)	0.5180	
No	391/ 525 (74.5)	354/ 505 (70.1)	1.06 (0.98, 1.15)	0.1175	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	379 (69.2)	336 (64.0)
Number of censored subjects, n (%)	169 (30.8)	189 (36.0)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.08 (0.99, 1.18)	
p-value	0.0741	
Odds Ratio (95% CI) [1]	1.26 (0.98, 1.63)	
p-value	0.0733	
Risk Difference (95% CI) [1]	5.16 (-0.48, 10.80)	
p-value	0.0729	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.7356
< 65	249/ 360 (69.2)	223/ 352 (63.4)	1.09 (0.98, 1.21)	0.1019	
>= 65	130/ 188 (69.1)	113/ 173 (65.3)	1.06 (0.92, 1.22)	0.4398	
Sex					0.4518
Male	169/ 249 (67.9)	178/ 274 (65.0)	1.04 (0.92, 1.18)	0.4815	
Female	210/ 299 (70.2)	158/ 251 (62.9)	1.12 (0.99, 1.26)	0.0742	
Region					0.8935
US	195/ 323 (60.4)	152/ 272 (55.9)	1.08 (0.94, 1.24)	0.2714	
Europe	129/ 158 (81.6)	126/ 173 (72.8)	1.12 (1.00, 1.26)	0.0562	
Other	55/ 67 (82.1)	58/ 80 (72.5)	1.13 (0.95, 1.35)	0.1648	
COVID-19 vaccination status within six months prior to randomization					0.4724
Yes	57/ 74 (77.0)	59/ 78 (75.6)	1.02 (0.85, 1.22)	0.8407	
No	322/ 474 (67.9)	277/ 447 (62.0)	1.10 (1.00, 1.21)	0.0590	
Prior SARS-CoV-2 infection within six months prior to randomization					0.8062
Yes	19/ 24 (79.2)	19/ 27 (70.4)	1.13 (0.82, 1.55)	0.4698	
No	360/ 524 (68.7)	317/ 498 (63.7)	1.08 (0.99, 1.18)	0.0892	
AZD7442 use within 12 months prior to randomization					0.6244
Yes	72/ 100 (72.0)	68/ 98 (69.4)	1.04 (0.87, 1.24)	0.6866	
No	307/ 448 (68.5)	268/ 427 (62.8)	1.09 (0.99, 1.20)	0.0738	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.5036
Yes	73/ 94 (77.7)	76/ 101 (75.2)	1.03 (0.88, 1.21)	0.6914	
No	306/ 454 (67.4)	260/ 424 (61.3)	1.10 (1.00, 1.21)	0.0613	
Solid organ or stem cell transplants					0.0582
Yes	175/ 268 (65.3)	173/ 263 (65.8)	0.99 (0.88, 1.12)	0.9072	
No	204/ 280 (72.9)	163/ 262 (62.2)	1.17 (1.04, 1.32)	0.0089	
Solid tumor cancer and on active treatment					0.6653
Yes	11/ 18 (61.1)	10/ 20 (50.0)	1.22 (0.69, 2.17)	0.4922	
No	368/ 530 (69.4)	326/ 505 (64.6)	1.08 (0.99, 1.17)	0.0961	
Taking immunosuppressive medicines					0.4353
Yes	332/ 491 (67.6)	293/ 464 (63.1)	1.07 (0.98, 1.17)	0.1478	
No	47/ 57 (82.5)	43/ 61 (70.5)	1.17 (0.96, 1.43)	0.1277	
Electrocardiogram (ECG) interpretation					0.8562
Normal	237/ 328 (72.3)	217/ 332 (65.4)	1.11 (1.00, 1.23)	0.0566	
Abnormal	118/ 184 (64.1)	101/ 171 (59.1)	1.09 (0.92, 1.28)	0.3285	
Body Mass Index					0.2661
<30 kg/m2	245/ 348 (70.4)	232/ 368 (63.0)	1.12 (1.01, 1.24)	0.0370	
>=30 kg/m2	132/ 198 (66.7)	100/ 151 (66.2)	1.01 (0.87, 1.17)	0.9311	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.7703
Yes	81/ 100 (81.0)	69/ 94 (73.4)	1.10 (0.95, 1.29)	0.2111	
No	298/ 448 (66.5)	267/ 431 (61.9)	1.07 (0.97, 1.19)	0.1587	
Moderate or severe secondary Immunodeficiency					0.7538
Yes	16/ 23 (69.6)	12/ 20 (60.0)	1.16 (0.74, 1.82)	0.5180	
No	363/ 525 (69.1)	324/ 505 (64.2)	1.08 (0.99, 1.18)	0.0907	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	80 (14.6)	68 (13.0)
Number of censored subjects, n (%)	468 (85.4)	457 (87.0)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.13 (0.83, 1.52)	
p-value	0.4349	
Odds Ratio (95% CI) [1]	1.15 (0.81, 1.63)	
p-value	0.4346	
Risk Difference (95% CI) [1]	1.65 (-2.48, 5.77)	
p-value	0.4338	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.1050
< 65	42/ 360 (11.7)	45/ 352 (12.8)	0.91 (0.62, 1.35)	0.6491	
>= 65	38/ 188 (20.2)	23/ 173 (13.3)	1.52 (0.95, 2.44)	0.0838	
Sex					0.8064
Male	39/ 249 (15.7)	39/ 274 (14.2)	1.10 (0.73, 1.66)	0.6469	
Female	41/ 299 (13.7)	29/ 251 (11.6)	1.19 (0.76, 1.85)	0.4506	
Region					0.3581
US	44/ 323 (13.6)	35/ 272 (12.9)	1.06 (0.70, 1.60)	0.7871	
Europe	24/ 158 (15.2)	26/ 173 (15.0)	1.01 (0.61, 1.69)	0.9674	
Other	12/ 67 (17.9)	7/ 80 (8.8)	2.05 (0.85, 4.90)	0.1081	
COVID-19 vaccination status within six months prior to randomization					0.2244
Yes	7/ 74 (9.5)	11/ 78 (14.1)	0.67 (0.27, 1.64)	0.3806	
No	73/ 474 (15.4)	57/ 447 (12.8)	1.21 (0.88, 1.67)	0.2497	
Prior SARS-CoV-2 infection within six months prior to randomization					0.9962
Yes	4/ 24 (16.7)	4/ 27 (14.8)	1.13 (0.32, 4.01)	0.8560	
No	76/ 524 (14.5)	64/ 498 (12.9)	1.13 (0.83, 1.54)	0.4430	
AZD7442 use within 12 months prior to randomization					0.8174
Yes	15/ 100 (15.0)	14/ 98 (14.3)	1.05 (0.54, 2.06)	0.8870	
No	65/ 448 (14.5)	54/ 427 (12.6)	1.15 (0.82, 1.60)	0.4224	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.2868
Yes	11/ 94 (11.7)	15/ 101 (14.9)	0.79 (0.38, 1.63)	0.5197	
No	69/ 454 (15.2)	53/ 424 (12.5)	1.22 (0.87, 1.70)	0.2494	
Solid organ or stem cell transplants					0.3989
Yes	47/ 268 (17.5)	45/ 263 (17.1)	1.02 (0.71, 1.49)	0.8966	
No	33/ 280 (11.8)	23/ 262 (8.8)	1.34 (0.81, 2.22)	0.2530	
Solid tumor cancer and on active treatment					0.2682
Yes	6/ 18 (33.3)	3/ 20 (15.0)	2.22 (0.65, 7.61)	0.2036	
No	74/ 530 (14.0)	65/ 505 (12.9)	1.08 (0.80, 1.48)	0.6071	
Taking immunosuppressive medicines					0.8958
Yes	71/ 491 (14.5)	59/ 464 (12.7)	1.14 (0.82, 1.57)	0.4326	
No	9/ 57 (15.8)	9/ 61 (14.8)	1.07 (0.46, 2.50)	0.8758	
Electrocardiogram (ECG) interpretation					0.5581
Normal	46/ 328 (14.0)	43/ 332 (13.0)	1.08 (0.74, 1.59)	0.6868	
Abnormal	31/ 184 (16.8)	22/ 171 (12.9)	1.31 (0.79, 2.17)	0.2954	
Body Mass Index					0.6797
<30 kg/m2	46/ 348 (13.2)	45/ 368 (12.2)	1.08 (0.74, 1.59)	0.6910	
>=30 kg/m2	34/ 198 (17.2)	21/ 151 (13.9)	1.23 (0.75, 2.04)	0.4095	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.4977
Yes	19/ 100 (19.0)	13/ 94 (13.8)	1.37 (0.72, 2.62)	0.3359	
No	61/ 448 (13.6)	55/ 431 (12.8)	1.07 (0.76, 1.50)	0.7082	
Moderate or severe secondary Immunodeficiency					0.8229
Yes	7/ 23 (30.4)	6/ 20 (30.0)	1.01 (0.41, 2.52)	0.9753	
No	73/ 525 (13.9)	62/ 505 (12.3)	1.13 (0.83, 1.55)	0.4396	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	72 (13.1)	61 (11.6)
Number of censored subjects, n (%)	476 (86.9)	464 (88.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.13 (0.82, 1.56)	
p-value	0.4507	
Odds Ratio (95% CI) [1]	1.15 (0.80, 1.66)	
p-value	0.4504	
Risk Difference (95% CI) [1]	1.52 (-2.42, 5.46)	
p-value	0.4495	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.1227
< 65	36/ 360 (10.0)	39/ 352 (11.1)	0.90 (0.59, 1.39)	0.6391	
>= 65	36/ 188 (19.1)	22/ 173 (12.7)	1.51 (0.92, 2.45)	0.1006	
Sex					0.9354
Male	36/ 249 (14.5)	35/ 274 (12.8)	1.13 (0.73, 1.74)	0.5746	
Female	36/ 299 (12.0)	26/ 251 (10.4)	1.16 (0.72, 1.87)	0.5354	
Region					0.4469
US	41/ 323 (12.7)	31/ 272 (11.4)	1.11 (0.72, 1.73)	0.6295	
Europe	20/ 158 (12.7)	23/ 173 (13.3)	0.95 (0.54, 1.67)	0.8634	
Other	11/ 67 (16.4)	7/ 80 (8.8)	1.88 (0.77, 4.57)	0.1659	
COVID-19 vaccination status within six months prior to randomization					0.2065
Yes	6/ 74 (8.1)	10/ 78 (12.8)	0.63 (0.24, 1.65)	0.3500	
No	66/ 474 (13.9)	51/ 447 (11.4)	1.22 (0.87, 1.72)	0.2534	
Prior SARS-CoV-2 infection within six months prior to randomization					0.9907
Yes	4/ 24 (16.7)	4/ 27 (14.8)	1.13 (0.32, 4.01)	0.8560	
No	68/ 524 (13.0)	57/ 498 (11.4)	1.13 (0.82, 1.58)	0.4557	
AZD7442 use within 12 months prior to randomization					0.5079
Yes	12/ 100 (12.0)	13/ 98 (13.3)	0.90 (0.43, 1.88)	0.7888	
No	60/ 448 (13.4)	48/ 427 (11.2)	1.19 (0.83, 1.70)	0.3345	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.2695
Yes	10/ 94 (10.6)	14/ 101 (13.9)	0.77 (0.36, 1.64)	0.4957	
No	62/ 454 (13.7)	47/ 424 (11.1)	1.23 (0.86, 1.76)	0.2497	
Solid organ or stem cell transplants					0.5756
Yes	42/ 268 (15.7)	39/ 263 (14.8)	1.06 (0.71, 1.58)	0.7872	
No	30/ 280 (10.7)	22/ 262 (8.4)	1.28 (0.76, 2.15)	0.3617	
Solid tumor cancer and on active treatment					0.2698
Yes	6/ 18 (33.3)	3/ 20 (15.0)	2.22 (0.65, 7.61)	0.2036	
No	66/ 530 (12.5)	58/ 505 (11.5)	1.08 (0.78, 1.51)	0.6320	
Taking immunosuppressive medicines					0.8971
Yes	64/ 491 (13.0)	53/ 464 (11.4)	1.14 (0.81, 1.61)	0.4482	
No	8/ 57 (14.0)	8/ 61 (13.1)	1.07 (0.43, 2.66)	0.8840	
Electrocardiogram (ECG) interpretation					0.4950
Normal	40/ 328 (12.2)	38/ 332 (11.4)	1.07 (0.70, 1.62)	0.7656	
Abnormal	29/ 184 (15.8)	20/ 171 (11.7)	1.35 (0.79, 2.29)	0.2702	
Body Mass Index					0.7453
<30 kg/m2	44/ 348 (12.6)	39/ 368 (10.6)	1.19 (0.80, 1.79)	0.3934	
>=30 kg/m2	28/ 198 (14.1)	20/ 151 (13.2)	1.07 (0.63, 1.82)	0.8098	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.5589
Yes	16/ 100 (16.0)	11/ 94 (11.7)	1.37 (0.67, 2.79)	0.3906	
No	56/ 448 (12.5)	50/ 431 (11.6)	1.08 (0.75, 1.54)	0.6825	
Moderate or severe secondary Immunodeficiency					0.8184
Yes	7/ 23 (30.4)	6/ 20 (30.0)	1.01 (0.41, 2.52)	0.9753	
No	65/ 525 (12.4)	55/ 505 (10.9)	1.14 (0.81, 1.59)	0.4568	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	76 (13.9)	70 (13.3)
Number of censored subjects, n (%)	472 (86.1)	455 (86.7)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.04 (0.77, 1.41)	
p-value	0.7983	
Odds Ratio (95% CI) [1]	1.05 (0.74, 1.48)	
p-value	0.7982	
Risk Difference (95% CI) [1]	0.54 (-3.57, 4.64)	
p-value	0.7982	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.0549
< 65	40/ 360 (11.1)	48/ 352 (13.6)	0.81 (0.55, 1.21)	0.3071	
>= 65	36/ 188 (19.1)	22/ 173 (12.7)	1.51 (0.92, 2.45)	0.1006	
Sex					0.5190
Male	39/ 249 (15.7)	44/ 274 (16.1)	0.98 (0.66, 1.45)	0.9016	
Female	37/ 299 (12.4)	26/ 251 (10.4)	1.19 (0.74, 1.92)	0.4609	
Region					0.5988
US	41/ 323 (12.7)	30/ 272 (11.0)	1.15 (0.74, 1.79)	0.5336	
Europe	23/ 158 (14.6)	29/ 173 (16.8)	0.87 (0.53, 1.44)	0.5824	
Other	12/ 67 (17.9)	11/ 80 (13.8)	1.30 (0.61, 2.76)	0.4903	
COVID-19 vaccination status within six months prior to randomization					0.4349
Yes	7/ 74 (9.5)	10/ 78 (12.8)	0.74 (0.30, 1.84)	0.5135	
No	69/ 474 (14.6)	60/ 447 (13.4)	1.08 (0.79, 1.49)	0.6203	
Prior SARS-CoV-2 infection within six months prior to randomization					0.7626
Yes	3/ 24 (12.5)	4/ 27 (14.8)	0.84 (0.21, 3.40)	0.8110	
No	73/ 524 (13.9)	66/ 498 (13.3)	1.05 (0.77, 1.43)	0.7519	
AZD7442 use within 12 months prior to randomization					0.9641
Yes	14/ 100 (14.0)	13/ 98 (13.3)	1.06 (0.52, 2.13)	0.8803	
No	62/ 448 (13.8)	57/ 427 (13.3)	1.04 (0.74, 1.45)	0.8325	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.3945
Yes	10/ 94 (10.6)	14/ 101 (13.9)	0.77 (0.36, 1.64)	0.4957	
No	66/ 454 (14.5)	56/ 424 (13.2)	1.10 (0.79, 1.53)	0.5695	
Solid organ or stem cell transplants					0.3970
Yes	42/ 268 (15.7)	44/ 263 (16.7)	0.94 (0.64, 1.38)	0.7407	
No	34/ 280 (12.1)	26/ 262 (9.9)	1.22 (0.76, 1.98)	0.4119	
Solid tumor cancer and on active treatment					0.2319
Yes	7/ 18 (38.9)	4/ 20 (20.0)	1.94 (0.68, 5.56)	0.2147	
No	69/ 530 (13.0)	66/ 505 (13.1)	1.00 (0.73, 1.36)	0.9808	
Taking immunosuppressive medicines					0.9475
Yes	67/ 491 (13.6)	61/ 464 (13.1)	1.04 (0.75, 1.43)	0.8210	
No	9/ 57 (15.8)	9/ 61 (14.8)	1.07 (0.46, 2.50)	0.8758	
Electrocardiogram (ECG) interpretation					0.5797
Normal	43/ 328 (13.1)	43/ 332 (13.0)	1.01 (0.68, 1.50)	0.9519	
Abnormal	30/ 184 (16.3)	23/ 171 (13.5)	1.21 (0.73, 2.00)	0.4522	
Body Mass Index					0.3216
<30 kg/m2	41/ 348 (11.8)	47/ 368 (12.8)	0.92 (0.62, 1.37)	0.6869	
>=30 kg/m2	35/ 198 (17.7)	21/ 151 (13.9)	1.27 (0.77, 2.09)	0.3450	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.4704
Yes	19/ 100 (19.0)	14/ 94 (14.9)	1.28 (0.68, 2.40)	0.4489	
No	57/ 448 (12.7)	56/ 431 (13.0)	0.98 (0.69, 1.38)	0.9049	
Moderate or severe secondary Immunodeficiency					0.4903
Yes	4/ 23 (17.4)	5/ 20 (25.0)	0.70 (0.22, 2.24)	0.5433	
No	72/ 525 (13.7)	65/ 505 (12.9)	1.07 (0.78, 1.46)	0.6905	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	69 (12.6)	63 (12.0)
Number of censored subjects, n (%)	479 (87.4)	462 (88.0)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.05 (0.76, 1.44)	
p-value	0.7682	
Odds Ratio (95% CI) [1]	1.06 (0.73, 1.52)	
p-value	0.7682	
Risk Difference (95% CI) [1]	0.59 (-3.34, 4.52)	
p-value	0.7681	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.0722
< 65	35/ 360 (9.7)	42/ 352 (11.9)	0.81 (0.53, 1.24)	0.3436	
>= 65	34/ 188 (18.1)	21/ 173 (12.1)	1.49 (0.90, 2.46)	0.1205	
Sex					0.7004
Male	36/ 249 (14.5)	39/ 274 (14.2)	1.02 (0.67, 1.54)	0.9417	
Female	33/ 299 (11.0)	24/ 251 (9.6)	1.15 (0.70, 1.90)	0.5726	
Region					0.5609
US	39/ 323 (12.1)	27/ 272 (9.9)	1.22 (0.77, 1.93)	0.4074	
Europe	19/ 158 (12.0)	25/ 173 (14.5)	0.83 (0.48, 1.45)	0.5173	
Other	11/ 67 (16.4)	11/ 80 (13.8)	1.19 (0.55, 2.58)	0.6518	
COVID-19 vaccination status within six months prior to randomization					0.5839
Yes	7/ 74 (9.5)	9/ 78 (11.5)	0.82 (0.32, 2.09)	0.6771	
No	62/ 474 (13.1)	54/ 447 (12.1)	1.08 (0.77, 1.52)	0.6479	
Prior SARS-CoV-2 infection within six months prior to randomization					0.7515
Yes	3/ 24 (12.5)	4/ 27 (14.8)	0.84 (0.21, 3.40)	0.8110	
No	66/ 524 (12.6)	59/ 498 (11.8)	1.06 (0.77, 1.48)	0.7153	
AZD7442 use within 12 months prior to randomization					0.8437
Yes	12/ 100 (12.0)	12/ 98 (12.2)	0.98 (0.46, 2.07)	0.9579	
No	57/ 448 (12.7)	51/ 427 (11.9)	1.07 (0.75, 1.52)	0.7262	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.5079
Yes	10/ 94 (10.6)	13/ 101 (12.9)	0.83 (0.38, 1.79)	0.6299	
No	59/ 454 (13.0)	50/ 424 (11.8)	1.10 (0.77, 1.57)	0.5893	
Solid organ or stem cell transplants					0.6135
Yes	38/ 268 (14.2)	38/ 263 (14.4)	0.98 (0.65, 1.49)	0.9293	
No	31/ 280 (11.1)	25/ 262 (9.5)	1.16 (0.70, 1.91)	0.5594	
Solid tumor cancer and on active treatment					0.2381
Yes	7/ 18 (38.9)	4/ 20 (20.0)	1.94 (0.68, 5.56)	0.2147	
No	62/ 530 (11.7)	59/ 505 (11.7)	1.00 (0.72, 1.40)	0.9940	
Taking immunosuppressive medicines					0.9665
Yes	61/ 491 (12.4)	55/ 464 (11.9)	1.05 (0.74, 1.47)	0.7875	
No	8/ 57 (14.0)	8/ 61 (13.1)	1.07 (0.43, 2.66)	0.8840	
Electrocardiogram (ECG) interpretation					0.4423
Normal	37/ 328 (11.3)	38/ 332 (11.4)	0.99 (0.64, 1.51)	0.9467	
Abnormal	29/ 184 (15.8)	21/ 171 (12.3)	1.28 (0.76, 2.16)	0.3485	
Body Mass Index					0.8390
<30 kg/m2	40/ 348 (11.5)	41/ 368 (11.1)	1.03 (0.68, 1.55)	0.8815	
>=30 kg/m2	29/ 198 (14.6)	20/ 151 (13.2)	1.11 (0.65, 1.88)	0.7093	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.5710
Yes	16/ 100 (16.0)	12/ 94 (12.8)	1.25 (0.63, 2.51)	0.5234	
No	53/ 448 (11.8)	51/ 431 (11.8)	1.00 (0.70, 1.43)	0.9991	
Moderate or severe secondary Immunodeficiency					0.4804
Yes	4/ 23 (17.4)	5/ 20 (25.0)	0.70 (0.22, 2.24)	0.5433	
No	65/ 525 (12.4)	58/ 505 (11.5)	1.08 (0.77, 1.50)	0.6578	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AE - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	393 (71.7)	355 (67.6)
Number of censored subjects, n (%)	155 (28.3)	170 (32.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.06 (0.98, 1.15)	
p-value	0.1454	
Odds Ratio (95% CI) [1]	1.21 (0.94, 1.58)	
p-value	0.1446	
Risk Difference (95% CI) [1]	4.10 (-1.40, 9.60)	
p-value	0.1443	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					0.2476
< 65	267/ 360 (74.2)	238/ 352 (67.6)	1.10 (1.00, 1.21)	0.0552	
>= 65	126/ 188 (67.0)	117/ 173 (67.6)	0.99 (0.86, 1.14)	0.9019	
Sex					0.7547
Male	178/ 249 (71.5)	187/ 274 (68.2)	1.05 (0.94, 1.17)	0.4197	
Female	215/ 299 (71.9)	168/ 251 (66.9)	1.07 (0.96, 1.20)	0.2104	
Region					0.8376
US	202/ 323 (62.5)	161/ 272 (59.2)	1.06 (0.93, 1.20)	0.4063	
Europe	134/ 158 (84.8)	133/ 173 (76.9)	1.10 (0.99, 1.23)	0.0669	
Other	57/ 67 (85.1)	61/ 80 (76.3)	1.12 (0.95, 1.31)	0.1748	
COVID-19 vaccination status within six months prior to randomization					0.4603
Yes	59/ 74 (79.7)	62/ 78 (79.5)	1.00 (0.85, 1.18)	0.9704	
No	334/ 474 (70.5)	293/ 447 (65.5)	1.07 (0.98, 1.18)	0.1111	
Prior SARS-CoV-2 infection within six months prior to randomization					0.6525
Yes	21/ 24 (87.5)	21/ 27 (77.8)	1.13 (0.87, 1.45)	0.3597	
No	372/ 524 (71.0)	334/ 498 (67.1)	1.06 (0.97, 1.15)	0.1760	
AZD7442 use within 12 months prior to randomization					0.3786
Yes	75/ 100 (75.0)	74/ 98 (75.5)	0.99 (0.85, 1.17)	0.9337	
No	318/ 448 (71.0)	281/ 427 (65.8)	1.08 (0.99, 1.18)	0.1010	
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.5273
Yes	77/ 94 (81.9)	81/ 101 (80.2)	1.02 (0.89, 1.17)	0.7596	
No	316/ 454 (69.6)	274/ 424 (64.6)	1.08 (0.98, 1.18)	0.1178	
Solid organ or stem cell transplants					0.5069
Yes	186/ 268 (69.4)	177/ 263 (67.3)	1.03 (0.92, 1.16)	0.6027	
No	207/ 280 (73.9)	178/ 262 (67.9)	1.09 (0.98, 1.21)	0.1267	
Solid tumor cancer and on active treatment					0.8856
Yes	9/ 18 (50.0)	9/ 20 (45.0)	1.11 (0.57, 2.17)	0.7577	
No	384/ 530 (72.5)	346/ 505 (68.5)	1.06 (0.98, 1.14)	0.1659	
Taking immunosuppressive medicines					0.6007
Yes	348/ 491 (70.9)	312/ 464 (67.2)	1.05 (0.97, 1.15)	0.2256	
No	45/ 57 (78.9)	43/ 61 (70.5)	1.12 (0.91, 1.38)	0.2916	
Electrocardiogram (ECG) interpretation					0.6064
Normal	248/ 328 (75.6)	228/ 332 (68.7)	1.10 (1.00, 1.21)	0.0475	
Abnormal	122/ 184 (66.3)	108/ 171 (63.2)	1.05 (0.90, 1.22)	0.5361	
Body Mass Index					0.6217
<30 kg/m2	252/ 348 (72.4)	248/ 368 (67.4)	1.07 (0.98, 1.18)	0.1431	
>=30 kg/m2	139/ 198 (70.2)	103/ 151 (68.2)	1.03 (0.89, 1.19)	0.6909	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AE - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					0.4511
Yes	78/ 100 (78.0)	73/ 94 (77.7)	1.00 (0.86, 1.17)	0.9545	
No	315/ 448 (70.3)	282/ 431 (65.4)	1.07 (0.98, 1.18)	0.1222	
Moderate or severe secondary Immunodeficiency					0.2729
Yes	15/ 23 (65.2)	9/ 20 (45.0)	1.45 (0.82, 2.56)	0.2012	
No	378/ 525 (72.0)	346/ 505 (68.5)	1.05 (0.97, 1.14)	0.2220	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to discontinuation of study treatment - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	4 (0.8)
Number of censored subjects, n (%)	548 (100.0)	521 (99.2)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.11 (0.01, 1.97)	
p-value	0.1326	
Odds Ratio (95% CI) [1]	0.11 (0.01, 1.97)	
p-value	0.1319	
Risk Difference (95% CI) [1]	-0.76 (-1.51, -0.02)	
p-value	0.0447	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to discontinuation of study treatment - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	0/ 360 (0.0)	2/ 352 (0.6)		
>= 65	0/ 188 (0.0)	2/ 173 (1.2)		
Sex				
Male	0/ 249 (0.0)	3/ 274 (1.1)		
Female	0/ 299 (0.0)	1/ 251 (0.4)		
Region				
US	0/ 323 (0.0)	1/ 272 (0.4)		
Europe	0/ 158 (0.0)	3/ 173 (1.7)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	1/ 78 (1.3)		
No	0/ 474 (0.0)	3/ 447 (0.7)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	0/ 524 (0.0)	4/ 498 (0.8)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	1/ 98 (1.0)		
No	0/ 448 (0.0)	3/ 427 (0.7)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	0/ 454 (0.0)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	0/ 268 (0.0)	0/ 263 (0.0)		
No	0/ 280 (0.0)	4/ 262 (1.5)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	0/ 530 (0.0)	4/ 505 (0.8)		
Taking immunosuppressive medicines				
Yes	0/ 491 (0.0)	3/ 464 (0.6)		
No	0/ 57 (0.0)	1/ 61 (1.6)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	3/ 332 (0.9)		
Abnormal	0/ 184 (0.0)	1/ 171 (0.6)		
Body Mass Index				
<30 kg/m2	0/ 348 (0.0)	3/ 368 (0.8)		
>=30 kg/m2	0/ 198 (0.0)	1/ 151 (0.7)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to discontinuation of study treatment - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	2/ 94 (2.1)			
No	0/ 448 (0.0)	2/ 431 (0.5)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	4/ 505 (0.8)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to death - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	4 (0.8)
Number of censored subjects, n (%)	543 (99.1)	521 (99.2)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.20 (0.32, 4.44)	
p-value	0.7873	
Odds Ratio (95% CI) [1]	1.20 (0.32, 4.49)	
p-value	0.7873	
Risk Difference (95% CI) [1]	0.15 (-0.94, 1.24)	
p-value	0.7866	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to death - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	3/ 360 (0.8)	1/ 352 (0.3)		
>= 65	2/ 188 (1.1)	3/ 173 (1.7)		
Sex				
Male	4/ 249 (1.6)	4/ 274 (1.5)		
Female	1/ 299 (0.3)	0/ 251 (0.0)		
Region				
US	4/ 323 (1.2)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	2/ 173 (1.2)		
Other	0/ 67 (0.0)	1/ 80 (1.3)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	1/ 78 (1.3)		
No	5/ 474 (1.1)	3/ 447 (0.7)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	5/ 524 (1.0)	4/ 498 (0.8)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	4/ 427 (0.9)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	5/ 454 (1.1)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	2/ 268 (0.7)	2/ 263 (0.8)		
No	3/ 280 (1.1)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	3/ 18 (16.7)	0/ 20 (0.0)		
No	2/ 530 (0.4)	4/ 505 (0.8)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	3/ 464 (0.6)		
No	0/ 57 (0.0)	1/ 61 (1.6)		
Electrocardiogram (ECG) interpretation				
Normal	2/ 328 (0.6)	2/ 332 (0.6)		
Abnormal	3/ 184 (1.6)	1/ 171 (0.6)		
Body Mass Index				
<30 kg/m2	3/ 348 (0.9)	3/ 368 (0.8)		
>=30 kg/m2	2/ 198 (1.0)	1/ 151 (0.7)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AE leading to death - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	1/ 100 (1.0)	3/ 94 (3.2)		
No	4/ 448 (0.9)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	0/ 23 (0.0)	0/ 20 (0.0)		
No	5/ 525 (1.0)	4/ 505 (0.8)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	4 (0.8)
Number of censored subjects, n (%)	543 (99.1)	521 (99.2)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.20 (0.32, 4.44)	
p-value	0.7873	
Odds Ratio (95% CI) [1]	1.20 (0.32, 4.49)	
p-value	0.7873	
Risk Difference (95% CI) [1]	0.15 (-0.94, 1.24)	
p-value	0.7866	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	3/ 173 (1.7)		
Sex				
Male	3/ 249 (1.2)	2/ 274 (0.7)		
Female	2/ 299 (0.7)	2/ 251 (0.8)		
Region				
US	3/ 323 (0.9)	2/ 272 (0.7)		
Europe	1/ 158 (0.6)	2/ 173 (1.2)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	5/ 474 (1.1)	4/ 447 (0.9)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	1/ 27 (3.7)		
No	4/ 524 (0.8)	3/ 498 (0.6)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	4/ 427 (0.9)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	1/ 101 (1.0)		
No	4/ 454 (0.9)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	5/ 268 (1.9)	1/ 263 (0.4)		
No	0/ 280 (0.0)	3/ 262 (1.1)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	1/ 20 (5.0)		
No	5/ 530 (0.9)	3/ 505 (0.6)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	4/ 464 (0.9)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	4/ 332 (1.2)		
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	5/ 348 (1.4)	3/ 368 (0.8)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	2/ 94 (2.1)		
No	5/ 448 (1.1)	2/ 431 (0.5)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	3/ 525 (0.6)	4/ 505 (0.8)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	3 (0.6)
Number of censored subjects, n (%)	543 (99.1)	522 (99.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.60 (0.38, 6.65)	
p-value	0.5202	
Odds Ratio (95% CI) [1]	1.60 (0.38, 6.74)	
p-value	0.5201	
Risk Difference (95% CI) [1]	0.34 (-0.68, 1.37)	
p-value	0.5142	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	2/ 173 (1.2)		
Sex				
Male	3/ 249 (1.2)	2/ 274 (0.7)		
Female	2/ 299 (0.7)	1/ 251 (0.4)		
Region				
US	3/ 323 (0.9)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	2/ 173 (1.2)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	5/ 474 (1.1)	3/ 447 (0.7)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	0/ 27 (0.0)		
No	4/ 524 (0.8)	3/ 498 (0.6)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	3/ 427 (0.7)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	0/ 101 (0.0)		
No	4/ 454 (0.9)	3/ 424 (0.7)		
Solid organ or stem cell transplants				
Yes	5/ 268 (1.9)	1/ 263 (0.4)		
No	0/ 280 (0.0)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	5/ 530 (0.9)	3/ 505 (0.6)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	3/ 464 (0.6)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	3/ 332 (0.9)		
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	5/ 348 (1.4)	2/ 368 (0.5)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	2/ 94 (2.1)		
No	5/ 448 (1.1)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	3/ 525 (0.6)	3/ 505 (0.6)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	4 (0.7)	2 (0.4)
Number of censored subjects, n (%)	544 (99.3)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.92 (0.35, 10.42)	
p-value	0.4516	
Odds Ratio (95% CI) [1]	1.92 (0.35, 10.54)	
p-value	0.4514	
Risk Difference (95% CI) [1]	0.35 (-0.54, 1.24)	
p-value	0.4403	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	1/ 360 (0.3)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	1/ 173 (0.6)		
Sex				
Male	2/ 249 (0.8)	1/ 274 (0.4)		
Female	2/ 299 (0.7)	1/ 251 (0.4)		
Region				
US	2/ 323 (0.6)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	1/ 173 (0.6)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	4/ 474 (0.8)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	0/ 27 (0.0)		
No	3/ 524 (0.6)	2/ 498 (0.4)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	4/ 448 (0.9)	2/ 427 (0.5)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	0/ 101 (0.0)		
No	3/ 454 (0.7)	2/ 424 (0.5)		
Solid organ or stem cell transplants				
Yes	4/ 268 (1.5)	1/ 263 (0.4)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	4/ 530 (0.8)	2/ 505 (0.4)		
Taking immunosuppressive medicines				
Yes	4/ 491 (0.8)	2/ 464 (0.4)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	2/ 332 (0.6)		
Abnormal	3/ 184 (1.6)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	4/ 348 (1.1)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	4/ 448 (0.9)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	2/ 525 (0.4)	2/ 505 (0.4)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	2 (0.4)
Number of censored subjects, n (%)	547 (99.8)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.48 (0.04, 5.27)	
p-value	0.5474	
Odds Ratio (95% CI) [1]	0.48 (0.04, 5.29)	
p-value	0.5473	
Risk Difference (95% CI) [1]	-0.20 (-0.84, 0.44)	
p-value	0.5412	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	1/ 360 (0.3)	0/ 352 (0.0)		
>= 65	0/ 188 (0.0)	2/ 173 (1.2)		
Sex				
Male	1/ 249 (0.4)	1/ 274 (0.4)		
Female	0/ 299 (0.0)	1/ 251 (0.4)		
Region				
US	1/ 323 (0.3)	1/ 272 (0.4)		
Europe	0/ 158 (0.0)	1/ 173 (0.6)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	1/ 474 (0.2)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	1/ 27 (3.7)		
No	1/ 524 (0.2)	1/ 498 (0.2)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	1/ 448 (0.2)	2/ 427 (0.5)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	1/ 101 (1.0)		
No	1/ 454 (0.2)	1/ 424 (0.2)		
Solid organ or stem cell transplants				
Yes	1/ 268 (0.4)	0/ 263 (0.0)		
No	0/ 280 (0.0)	2/ 262 (0.8)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	1/ 20 (5.0)		
No	1/ 530 (0.2)	1/ 505 (0.2)		
Taking immunosuppressive medicines				
Yes	1/ 491 (0.2)	2/ 464 (0.4)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	2/ 332 (0.6)		
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	1/ 348 (0.3)	2/ 368 (0.5)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	1/ 448 (0.2)	1/ 431 (0.2)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	2/ 505 (0.4)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	3 (0.6)
Number of censored subjects, n (%)	543 (99.1)	522 (99.4)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.60 (0.38, 6.65)	
p-value	0.5202	
Odds Ratio (95% CI) [1]	1.60 (0.38, 6.74)	
p-value	0.5201	
Risk Difference (95% CI) [1]	0.34 (-0.68, 1.37)	
p-value	0.5142	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	2/ 360 (0.6)	1/ 352 (0.3)			
>= 65	3/ 188 (1.6)	2/ 173 (1.2)			
Sex					
Male	3/ 249 (1.2)	1/ 274 (0.4)			
Female	2/ 299 (0.7)	2/ 251 (0.8)			
Region					
US	3/ 323 (0.9)	2/ 272 (0.7)			
Europe	1/ 158 (0.6)	1/ 173 (0.6)			
Other	1/ 67 (1.5)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	5/ 474 (1.1)	3/ 447 (0.7)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	1/ 24 (4.2)	1/ 27 (3.7)			
No	4/ 524 (0.8)	2/ 498 (0.4)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	5/ 448 (1.1)	3/ 427 (0.7)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	1/ 94 (1.1)	1/ 101 (1.0)			
No	4/ 454 (0.9)	2/ 424 (0.5)			
Solid organ or stem cell transplants					
Yes	5/ 268 (1.9)	1/ 263 (0.4)			
No	0/ 280 (0.0)	2/ 262 (0.8)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	1/ 20 (5.0)			
No	5/ 530 (0.9)	2/ 505 (0.4)			
Taking immunosuppressive medicines					
Yes	5/ 491 (1.0)	3/ 464 (0.6)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	1/ 328 (0.3)	3/ 332 (0.9)			
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	5/ 348 (1.4)	2/ 368 (0.5)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	5/ 448 (1.1)	2/ 431 (0.5)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	3/ 525 (0.6)	3/ 505 (0.6)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	5 (0.9)	2 (0.4)
Number of censored subjects, n (%)	543 (99.1)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	2.40 (0.47, 12.29)	
p-value	0.2952	
Odds Ratio (95% CI) [1]	2.41 (0.47, 12.47)	
p-value	0.2949	
Risk Difference (95% CI) [1]	0.53 (-0.42, 1.49)	
p-value	0.2752	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	2/ 360 (0.6)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	1/ 173 (0.6)		
Sex				
Male	3/ 249 (1.2)	1/ 274 (0.4)		
Female	2/ 299 (0.7)	1/ 251 (0.4)		
Region				
US	3/ 323 (0.9)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	1/ 173 (0.6)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	5/ 474 (1.1)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	0/ 27 (0.0)		
No	4/ 524 (0.8)	2/ 498 (0.4)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	5/ 448 (1.1)	2/ 427 (0.5)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	0/ 101 (0.0)		
No	4/ 454 (0.9)	2/ 424 (0.5)		
Solid organ or stem cell transplants				
Yes	5/ 268 (1.9)	1/ 263 (0.4)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	5/ 530 (0.9)	2/ 505 (0.4)		
Taking immunosuppressive medicines				
Yes	5/ 491 (1.0)	2/ 464 (0.4)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	2/ 332 (0.6)		
Abnormal	4/ 184 (2.2)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	5/ 348 (1.4)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	5/ 448 (1.1)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	3/ 525 (0.6)	2/ 505 (0.4)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	4 (0.7)	2 (0.4)
Number of censored subjects, n (%)	544 (99.3)	523 (99.6)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	1.92 (0.35, 10.42)	
p-value	0.4516	
Odds Ratio (95% CI) [1]	1.92 (0.35, 10.54)	
p-value	0.4514	
Risk Difference (95% CI) [1]	0.35 (-0.54, 1.24)	
p-value	0.4403	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	1/ 360 (0.3)	1/ 352 (0.3)		
>= 65	3/ 188 (1.6)	1/ 173 (0.6)		
Sex				
Male	2/ 249 (0.8)	1/ 274 (0.4)		
Female	2/ 299 (0.7)	1/ 251 (0.4)		
Region				
US	2/ 323 (0.6)	1/ 272 (0.4)		
Europe	1/ 158 (0.6)	1/ 173 (0.6)		
Other	1/ 67 (1.5)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	4/ 474 (0.8)	2/ 447 (0.4)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	1/ 24 (4.2)	0/ 27 (0.0)		
No	3/ 524 (0.6)	2/ 498 (0.4)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	4/ 448 (0.9)	2/ 427 (0.5)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	1/ 94 (1.1)	0/ 101 (0.0)		
No	3/ 454 (0.7)	2/ 424 (0.5)		
Solid organ or stem cell transplants				
Yes	4/ 268 (1.5)	1/ 263 (0.4)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	4/ 530 (0.8)	2/ 505 (0.4)		
Taking immunosuppressive medicines				
Yes	4/ 491 (0.8)	2/ 464 (0.4)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	1/ 328 (0.3)	2/ 332 (0.6)		
Abnormal	3/ 184 (1.6)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	4/ 348 (1.1)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	4/ 448 (0.9)	1/ 431 (0.2)		
Moderate or severe secondary Immunodeficiency				
Yes	2/ 23 (8.7)	0/ 20 (0.0)		
No	2/ 525 (0.4)	2/ 505 (0.4)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Number of censored subjects, n (%)	547 (99.8)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.96 (0.06, 15.28)	
p-value	0.9758	
Odds Ratio (95% CI) [1]	0.96 (0.06, 15.35)	
p-value	0.9758	
Risk Difference (95% CI) [1]	-0.01 (-0.52, 0.51)	
p-value	0.9758	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	1/ 360 (0.3)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	1/ 173 (0.6)			
Sex					
Male	1/ 249 (0.4)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	1/ 251 (0.4)			
Region					
US	1/ 323 (0.3)	1/ 272 (0.4)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	1/ 474 (0.2)	1/ 447 (0.2)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	1/ 27 (3.7)			
No	1/ 524 (0.2)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	1/ 448 (0.2)	1/ 427 (0.2)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	1/ 101 (1.0)			
No	1/ 454 (0.2)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	1/ 268 (0.4)	0/ 263 (0.0)			
No	0/ 280 (0.0)	1/ 262 (0.4)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	1/ 20 (5.0)			
No	1/ 530 (0.2)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	1/ 491 (0.2)	1/ 464 (0.2)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	1/ 332 (0.3)			
Abnormal	1/ 184 (0.5)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	1/ 348 (0.3)	1/ 368 (0.3)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Cardiovascular and thrombotic events - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	0/ 94 (0.0)			
No	1/ 448 (0.2)	1/ 431 (0.2)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	1/ 525 (0.2)	1/ 505 (0.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.32 (0.01, 7.82)	
p-value	0.4843	
Odds Ratio (95% CI) [1]	0.32 (0.01, 7.84)	
p-value	0.4841	
Risk Difference (95% CI) [1]	-0.19 (-0.56, 0.18)	
p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	0/ 360 (0.0)	0/ 352 (0.0)		
>= 65	0/ 188 (0.0)	1/ 173 (0.6)		
Sex				
Male	0/ 249 (0.0)	1/ 274 (0.4)		
Female	0/ 299 (0.0)	0/ 251 (0.0)		
Region				
US	0/ 323 (0.0)	0/ 272 (0.0)		
Europe	0/ 158 (0.0)	1/ 173 (0.6)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	0/ 474 (0.0)	1/ 447 (0.2)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	0/ 524 (0.0)	1/ 498 (0.2)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	0/ 448 (0.0)	1/ 427 (0.2)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	0/ 101 (0.0)		
No	0/ 454 (0.0)	1/ 424 (0.2)		
Solid organ or stem cell transplants				
Yes	0/ 268 (0.0)	0/ 263 (0.0)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	0/ 530 (0.0)	1/ 505 (0.2)		
Taking immunosuppressive medicines				
Yes	0/ 491 (0.0)	1/ 464 (0.2)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	1/ 332 (0.3)		
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	1/ 505 (0.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.32 (0.01, 7.82)	
p-value	0.4843	
Odds Ratio (95% CI) [1]	0.32 (0.01, 7.84)	
p-value	0.4841	
Risk Difference (95% CI) [1]	-0.19 (-0.56, 0.18)	
p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	0/ 360 (0.0)	0/ 352 (0.0)		
>= 65	0/ 188 (0.0)	1/ 173 (0.6)		
Sex				
Male	0/ 249 (0.0)	1/ 274 (0.4)		
Female	0/ 299 (0.0)	0/ 251 (0.0)		
Region				
US	0/ 323 (0.0)	0/ 272 (0.0)		
Europe	0/ 158 (0.0)	1/ 173 (0.6)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	0/ 474 (0.0)	1/ 447 (0.2)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	0/ 524 (0.0)	1/ 498 (0.2)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	0/ 448 (0.0)	1/ 427 (0.2)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	0/ 101 (0.0)		
No	0/ 454 (0.0)	1/ 424 (0.2)		
Solid organ or stem cell transplants				
Yes	0/ 268 (0.0)	0/ 263 (0.0)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	0/ 530 (0.0)	1/ 505 (0.2)		
Taking immunosuppressive medicines				
Yes	0/ 491 (0.0)	1/ 464 (0.2)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	1/ 332 (0.3)		
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Serious AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	1/ 94 (1.1)		
No	0/ 448 (0.0)	0/ 431 (0.0)		
Moderate or severe secondary Immunodeficiency				
Yes	0/ 23 (0.0)	0/ 20 (0.0)		
No	0/ 525 (0.0)	1/ 505 (0.2)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	548 (100.0)	525 (100.0)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Age					
< 65	0/ 360 (0.0)	0/ 352 (0.0)			
>= 65	0/ 188 (0.0)	0/ 173 (0.0)			
Sex					
Male	0/ 249 (0.0)	0/ 274 (0.0)			
Female	0/ 299 (0.0)	0/ 251 (0.0)			
Region					
US	0/ 323 (0.0)	0/ 272 (0.0)			
Europe	0/ 158 (0.0)	0/ 173 (0.0)			
Other	0/ 67 (0.0)	0/ 80 (0.0)			
COVID-19 vaccination status within six months prior to randomization					
Yes	0/ 74 (0.0)	0/ 78 (0.0)			
No	0/ 474 (0.0)	0/ 447 (0.0)			
Prior SARS-CoV-2 infection within six months prior to randomization					
Yes	0/ 24 (0.0)	0/ 27 (0.0)			
No	0/ 524 (0.0)	0/ 498 (0.0)			
AZD7442 use within 12 months prior to randomization					
Yes	0/ 100 (0.0)	0/ 98 (0.0)			
No	0/ 448 (0.0)	0/ 427 (0.0)			
Prior COVID-19 vaccination or prior SARS-CoV-2 infection					
Yes	0/ 94 (0.0)	0/ 101 (0.0)			
No	0/ 454 (0.0)	0/ 424 (0.0)			
Solid organ or stem cell transplants					
Yes	0/ 268 (0.0)	0/ 263 (0.0)			
No	0/ 280 (0.0)	0/ 262 (0.0)			
Solid tumor cancer and on active treatment					
Yes	0/ 18 (0.0)	0/ 20 (0.0)			
No	0/ 530 (0.0)	0/ 505 (0.0)			
Taking immunosuppressive medicines					
Yes	0/ 491 (0.0)	0/ 464 (0.0)			
No	0/ 57 (0.0)	0/ 61 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 328 (0.0)	0/ 332 (0.0)			
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)			
Body Mass Index					
<30 kg/m2	0/ 348 (0.0)	0/ 368 (0.0)			
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Hematological malignancies				
Yes	0/ 100 (0.0)	0/ 94 (0.0)		
No	0/ 448 (0.0)	0/ 431 (0.0)		
Moderate or severe secondary Immunodeficiency				
Yes	0/ 23 (0.0)	0/ 20 (0.0)		
No	0/ 525 (0.0)	0/ 505 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

	AZD3152/AZD3152 (N=548)	Comparator (N=525)
Number of subjects with events, n (%)	0 (0.0)	1 (0.2)
Number of censored subjects, n (%)	548 (100.0)	524 (99.8)
Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
Relative Risk (95% CI) [1]	0.32 (0.01, 7.82)	
p-value	0.4843	
Odds Ratio (95% CI) [1]	0.32 (0.01, 7.84)	
p-value	0.4841	
Risk Difference (95% CI) [1]	-0.19 (-0.56, 0.18)	
p-value	0.3168	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 65	0/ 360 (0.0)	0/ 352 (0.0)		
>= 65	0/ 188 (0.0)	1/ 173 (0.6)		
Sex				
Male	0/ 249 (0.0)	1/ 274 (0.4)		
Female	0/ 299 (0.0)	0/ 251 (0.0)		
Region				
US	0/ 323 (0.0)	0/ 272 (0.0)		
Europe	0/ 158 (0.0)	1/ 173 (0.6)		
Other	0/ 67 (0.0)	0/ 80 (0.0)		
COVID-19 vaccination status within six months prior to randomization				
Yes	0/ 74 (0.0)	0/ 78 (0.0)		
No	0/ 474 (0.0)	1/ 447 (0.2)		
Prior SARS-CoV-2 infection within six months prior to randomization				
Yes	0/ 24 (0.0)	0/ 27 (0.0)		
No	0/ 524 (0.0)	1/ 498 (0.2)		
AZD7442 use within 12 months prior to randomization				
Yes	0/ 100 (0.0)	0/ 98 (0.0)		
No	0/ 448 (0.0)	1/ 427 (0.2)		
Prior COVID-19 vaccination or prior SARS-CoV-2 infection				
Yes	0/ 94 (0.0)	0/ 101 (0.0)		
No	0/ 454 (0.0)	1/ 424 (0.2)		
Solid organ or stem cell transplants				
Yes	0/ 268 (0.0)	0/ 263 (0.0)		
No	0/ 280 (0.0)	1/ 262 (0.4)		
Solid tumor cancer and on active treatment				
Yes	0/ 18 (0.0)	0/ 20 (0.0)		
No	0/ 530 (0.0)	1/ 505 (0.2)		
Taking immunosuppressive medicines				
Yes	0/ 491 (0.0)	1/ 464 (0.2)		
No	0/ 57 (0.0)	0/ 61 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 328 (0.0)	1/ 332 (0.3)		
Abnormal	0/ 184 (0.0)	0/ 171 (0.0)		
Body Mass Index				
<30 kg/m2	0/ 348 (0.0)	1/ 368 (0.3)		
>=30 kg/m2	0/ 198 (0.0)	0/ 151 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of Non-severe AESI: Anaphylaxis and other serious hypersensitivity reactions + immune-complex disease - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value [2]
Hematological malignancies					
Yes	0/ 100 (0.0)	1/ 94 (1.1)			
No	0/ 448 (0.0)	0/ 431 (0.0)			
Moderate or severe secondary Immunodeficiency					
Yes	0/ 23 (0.0)	0/ 20 (0.0)			
No	0/ 525 (0.0)	1/ 505 (0.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	18 (3.3)	7 (1.3)
	Number of censored subjects, n (%)	530 (96.7)	518 (98.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.46 (1.04, 5.85)	
	p-value	0.0410	
	Odds Ratio (95% CI) [1]	2.51 (1.04, 6.07)	
	p-value	0.0404	
	Risk Difference (95% CI) [1]	1.95 (0.17, 3.74)	
	p-value	0.0322	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Cardiac disorders	Number of subjects with events, n (%)	12 (2.2)	10 (1.9)
	Number of censored subjects, n (%)	536 (97.8)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.15 (0.50, 2.64)	
	p-value	0.7421	
	Odds Ratio (95% CI) [1]	1.15 (0.49, 2.69)	
	p-value	0.7421	
	Risk Difference (95% CI) [1]	0.29 (-1.41, 1.98)	
	p-value	0.7415	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	5 (0.9)	10 (1.9)
	Number of censored subjects, n (%)	543 (99.1)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.48 (0.16, 1.39)	
	p-value	0.1763	
	Odds Ratio (95% CI) [1]	0.47 (0.16, 1.40)	
	p-value	0.1758	
	Risk Difference (95% CI) [1]	-0.99 (-2.41, 0.42)	
	p-value	0.1691	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	55 (10.0)	61 (11.6)
	Number of censored subjects, n (%)	493 (90.0)	464 (88.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.86 (0.61, 1.22)	
	p-value	0.4045	
	Odds Ratio (95% CI) [1]	0.85 (0.58, 1.25)	
	p-value	0.4044	
	Risk Difference (95% CI) [1]	-1.58 (-5.30, 2.14)	
	p-value	0.4045	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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[1] Calculated using normal approximation (Wald).
NE: Not estimable

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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	22 (4.0)	30 (5.7)
	Number of censored subjects, n (%)	526 (96.0)	495 (94.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.70 (0.41, 1.20)	
	p-value	0.1975	
	Odds Ratio (95% CI) [1]	0.69 (0.39, 1.21)	
	p-value	0.1972	
	Risk Difference (95% CI) [1]	-1.70 (-4.28, 0.88)	
	p-value	0.1962	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	13 (2.4)	14 (2.7)
	Number of censored subjects, n (%)	535 (97.6)	511 (97.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.89 (0.42, 1.87)	
	p-value	0.7584	
	Odds Ratio (95% CI) [1]	0.89 (0.41, 1.91)	
	p-value	0.7584	
	Risk Difference (95% CI) [1]	-0.29 (-2.17, 1.58)	
	p-value	0.7585	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	90 (16.4)	103 (19.6)
	Number of censored subjects, n (%)	458 (83.6)	422 (80.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.84 (0.65, 1.08)	
	p-value	0.1738	
	Odds Ratio (95% CI) [1]	0.81 (0.59, 1.10)	
	p-value	0.1735	
	Risk Difference (95% CI) [1]	-3.20 (-7.80, 1.40)	
	p-value	0.1733	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Asthenia	Number of subjects with events, n (%)	17 (3.1)	16 (3.0)
	Number of censored subjects, n (%)	531 (96.9)	509 (97.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.02 (0.52, 1.99)	
	p-value	0.9587	
	Odds Ratio (95% CI) [1]	1.02 (0.51, 2.04)	
	p-value	0.9587	
	Risk Difference (95% CI) [1]	0.05 (-2.01, 2.12)	
	p-value	0.9587	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	23 (4.2)	40 (7.6)
	Number of censored subjects, n (%)	525 (95.8)	485 (92.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.55 (0.33, 0.91)	
	p-value	0.0191	
	Odds Ratio (95% CI) [1]	0.53 (0.31, 0.90)	
	p-value	0.0188	
	Risk Difference (95% CI) [1]	-3.42 (-6.24, -0.60)	
	p-value	0.0175	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Injection site pain	Number of subjects with events, n (%)	8 (1.5)	11 (2.1)
	Number of censored subjects, n (%)	540 (98.5)	514 (97.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.70 (0.28, 1.72)	
	p-value	0.4328	
	Odds Ratio (95% CI) [1]	0.69 (0.28, 1.73)	
	p-value	0.4326	
	Risk Difference (95% CI) [1]	-0.64 (-2.22, 0.95)	
	p-value	0.4318	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	19 (3.5)	14 (2.7)
	Number of censored subjects, n (%)	529 (96.5)	511 (97.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.30 (0.66, 2.57)	
	p-value	0.4492	
	Odds Ratio (95% CI) [1]	1.31 (0.65, 2.64)	
	p-value	0.4490	
	Risk Difference (95% CI) [1]	0.80 (-1.26, 2.86)	
	p-value	0.4464	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	172 (31.4)	154 (29.3)
	Number of censored subjects, n (%)	376 (68.6)	371 (70.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.07 (0.89, 1.28)	
	p-value	0.4650	
	Odds Ratio (95% CI) [1]	1.10 (0.85, 1.43)	
	p-value	0.4648	
	Risk Difference (95% CI) [1]	2.05 (-3.45, 7.55)	
	p-value	0.4644	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: COVID-19	Number of subjects with events, n (%)	33 (6.0)	60 (11.4)
	Number of censored subjects, n (%)	515 (94.0)	465 (88.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.53 (0.35, 0.79)	
	p-value	0.0021	
	Odds Ratio (95% CI) [1]	0.50 (0.32, 0.77)	
	p-value	0.0020	
	Risk Difference (95% CI) [1]	-5.41 (-8.78, -2.03)	
	p-value	0.0017	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Influenza	Number of subjects with events, n (%)	12 (2.2)	3 (0.6)
	Number of censored subjects, n (%)	536 (97.8)	522 (99.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	3.83 (1.09, 13.50)	
	p-value	0.0366	
	Odds Ratio (95% CI) [1]	3.90 (1.09, 13.88)	
	p-value	0.0360	
	Risk Difference (95% CI) [1]	1.62 (0.23, 3.00)	
	p-value	0.0220	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	16 (2.9)	13 (2.5)
	Number of censored subjects, n (%)	532 (97.1)	512 (97.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.18 (0.57, 2.43)	
	p-value	0.6547	
	Odds Ratio (95% CI) [1]	1.18 (0.56, 2.49)	
	p-value	0.6546	
	Risk Difference (95% CI) [1]	0.44 (-1.49, 2.38)	
	p-value	0.6537	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Rhinitis	Number of subjects with events, n (%)	7 (1.3)	10 (1.9)
	Number of censored subjects, n (%)	541 (98.7)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.67 (0.26, 1.75)	
	p-value	0.4139	
	Odds Ratio (95% CI) [1]	0.67 (0.25, 1.76)	
	p-value	0.4137	
	Risk Difference (95% CI) [1]	-0.63 (-2.13, 0.87)	
	p-value	0.4125	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	25 (4.6)	16 (3.0)
	Number of censored subjects, n (%)	523 (95.4)	509 (97.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.50 (0.81, 2.77)	
	p-value	0.1993	
	Odds Ratio (95% CI) [1]	1.52 (0.80, 2.88)	
	p-value	0.1987	
	Risk Difference (95% CI) [1]	1.51 (-0.77, 3.80)	
	p-value	0.1936	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	24 (4.4)	17 (3.2)
	Number of censored subjects, n (%)	524 (95.6)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.35 (0.74, 2.49)	
	p-value	0.3317	
	Odds Ratio (95% CI) [1]	1.37 (0.73, 2.58)	
	p-value	0.3313	
	Risk Difference (95% CI) [1]	1.14 (-1.15, 3.43)	
	p-value	0.3279	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	30 (5.5)	38 (7.2)
	Number of censored subjects, n (%)	518 (94.5)	487 (92.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.76 (0.48, 1.20)	
	p-value	0.2376	
	Odds Ratio (95% CI) [1]	0.74 (0.45, 1.22)	
	p-value	0.2373	
	Risk Difference (95% CI) [1]	-1.76 (-4.69, 1.16)	
	p-value	0.2369	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Investigations	Number of subjects with events, n (%)	15 (2.7)	8 (1.5)
	Number of censored subjects, n (%)	533 (97.3)	517 (98.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.80 (0.77, 4.20)	
	p-value	0.1767	
	Odds Ratio (95% CI) [1]	1.82 (0.76, 4.33)	
	p-value	0.1761	
	Risk Difference (95% CI) [1]	1.21 (-0.51, 2.94)	
	p-value	0.1672	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	21 (3.8)	21 (4.0)
	Number of censored subjects, n (%)	527 (96.2)	504 (96.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.53, 1.73)	
	p-value	0.8873	
	Odds Ratio (95% CI) [1]	0.96 (0.52, 1.77)	
	p-value	0.8873	
	Risk Difference (95% CI) [1]	-0.17 (-2.49, 2.15)	
	p-value	0.8873	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	48 (8.8)	49 (9.3)
	Number of censored subjects, n (%)	500 (91.2)	476 (90.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.94 (0.64, 1.37)	
	p-value	0.7430	
	Odds Ratio (95% CI) [1]	0.93 (0.61, 1.42)	
	p-value	0.7430	
	Risk Difference (95% CI) [1]	-0.57 (-4.01, 2.86)	
	p-value	0.7431	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia	Number of subjects with events, n (%)	10 (1.8)	19 (3.6)
	Number of censored subjects, n (%)	538 (98.2)	506 (96.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.50 (0.24, 1.07)	
	p-value	0.0760	
	Odds Ratio (95% CI) [1]	0.50 (0.23, 1.07)	
	p-value	0.0755	
	Risk Difference (95% CI) [1]	-1.79 (-3.75, 0.16)	
	p-value	0.0715	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	14 (2.6)	7 (1.3)
	Number of censored subjects, n (%)	534 (97.4)	518 (98.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (0.78, 4.71)	
	p-value	0.1564	
	Odds Ratio (95% CI) [1]	1.94 (0.78, 4.85)	
	p-value	0.1559	
	Risk Difference (95% CI) [1]	1.22 (-0.42, 2.87)	
	p-value	0.1457	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Nervous system disorders	Number of subjects with events, n (%)	54 (9.9)	55 (10.5)
	Number of censored subjects, n (%)	494 (90.1)	470 (89.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.94 (0.66, 1.34)	
	p-value	0.7360	
	Odds Ratio (95% CI) [1]	0.93 (0.63, 1.39)	
	p-value	0.7360	
	Risk Difference (95% CI) [1]	-0.62 (-4.24, 3.00)	
	p-value	0.7361	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	34 (6.2)	36 (6.9)
	Number of censored subjects, n (%)	514 (93.8)	489 (93.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.90 (0.58, 1.42)	
	p-value	0.6653	
	Odds Ratio (95% CI) [1]	0.90 (0.55, 1.46)	
	p-value	0.6653	
	Risk Difference (95% CI) [1]	-0.65 (-3.61, 2.31)	
	p-value	0.6654	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	12 (2.2)	13 (2.5)
	Number of censored subjects, n (%)	536 (97.8)	512 (97.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.88 (0.41, 1.92)	
	p-value	0.7560	
	Odds Ratio (95% CI) [1]	0.88 (0.40, 1.95)	
	p-value	0.7560	
	Risk Difference (95% CI) [1]	-0.29 (-2.09, 1.52)	
	p-value	0.7562	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	104 (19.0)	90 (17.1)
	Number of censored subjects, n (%)	444 (81.0)	435 (82.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.11 (0.86, 1.43)	
	p-value	0.4353	
	Odds Ratio (95% CI) [1]	1.13 (0.83, 1.55)	
	p-value	0.4351	
	Risk Difference (95% CI) [1]	1.84 (-2.77, 6.44)	
	p-value	0.4344	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	43 (7.8)	47 (9.0)
	Number of censored subjects, n (%)	505 (92.2)	478 (91.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.88 (0.59, 1.30)	
	p-value	0.5140	
	Odds Ratio (95% CI) [1]	0.87 (0.56, 1.33)	
	p-value	0.5140	
	Risk Difference (95% CI) [1]	-1.11 (-4.43, 2.22)	
	p-value	0.5141	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Number of subjects with events, n (%)	10 (1.8)	4 (0.8)
	Number of censored subjects, n (%)	538 (98.2)	521 (99.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.40 (0.76, 7.59)	
	p-value	0.1377	
	Odds Ratio (95% CI) [1]	2.42 (0.75, 7.77)	
	p-value	0.1371	
	Risk Difference (95% CI) [1]	1.06 (-0.28, 2.41)	
	p-value	0.1214	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Number of subjects with events, n (%)	25 (4.6)	11 (2.1)
	Number of censored subjects, n (%)	523 (95.4)	514 (97.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.18 (1.08, 4.38)	
	p-value	0.0291	
	Odds Ratio (95% CI) [1]	2.23 (1.09, 4.59)	
	p-value	0.0286	
	Risk Difference (95% CI) [1]	2.47 (0.33, 4.60)	
	p-value	0.0235	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Number of subjects with events, n (%)	29 (5.3)	18 (3.4)
	Number of censored subjects, n (%)	519 (94.7)	507 (96.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.54 (0.87, 2.75)	
	p-value	0.1396	
	Odds Ratio (95% CI) [1]	1.57 (0.86, 2.87)	
	p-value	0.1389	
	Risk Difference (95% CI) [1]	1.86 (-0.57, 4.30)	
	p-value	0.1339	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Rhinorrhoea	Number of subjects with events, n (%)	30 (5.5)	30 (5.7)
	Number of censored subjects, n (%)	518 (94.5)	495 (94.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.59, 1.57)	
	p-value	0.8643	
	Odds Ratio (95% CI) [1]	0.96 (0.57, 1.61)	
	p-value	0.8643	
	Risk Difference (95% CI) [1]	-0.24 (-2.99, 2.51)	
	p-value	0.8643	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	23 (4.2)	16 (3.0)
	Number of censored subjects, n (%)	525 (95.8)	509 (97.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.38 (0.74, 2.58)	
	p-value	0.3169	
	Odds Ratio (95% CI) [1]	1.39 (0.73, 2.67)	
	p-value	0.3165	
	Risk Difference (95% CI) [1]	1.15 (-1.08, 3.38)	
	p-value	0.3127	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Vascular disorders	Number of subjects with events, n (%)	19 (3.5)	16 (3.0)
	Number of censored subjects, n (%)	529 (96.5)	509 (97.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.14 (0.59, 2.19)	
	p-value	0.6992	
	Odds Ratio (95% CI) [1]	1.14 (0.58, 2.25)	
	p-value	0.6992	
	Risk Difference (95% CI) [1]	0.42 (-1.70, 2.54)	
	p-value	0.6986	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	5 (0.9)	11 (2.1)
	Number of censored subjects, n (%)	543 (99.1)	514 (97.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.44 (0.15, 1.24)	
	p-value	0.1208	
	Odds Ratio (95% CI) [1]	0.43 (0.15, 1.25)	
	p-value	0.1203	
	Risk Difference (95% CI) [1]	-1.18 (-2.64, 0.28)	
	p-value	0.1126	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Blood and lymphatic system disorders	Age					0.2769
	< 65	11/ 360 (3.1)	6/ 352 (1.7)	1.79 (0.67, 4.79)	0.2449	
	>= 65	7/ 188 (3.7)	1/ 173 (0.6)	6.44 (0.80, 51.82)	0.0800	
	Sex					0.1394
	Male	10/ 249 (4.0)	2/ 274 (0.7)	5.50 (1.22, 24.87)	0.0267	
	Female	8/ 299 (2.7)	5/ 251 (2.0)	1.34 (0.45, 4.05)	0.6007	
	Region					0.7944
	US	9/ 323 (2.8)	2/ 272 (0.7)	3.79 (0.83, 17.39)	0.0866	
	Europe	6/ 158 (3.8)	3/ 173 (1.7)	2.19 (0.56, 8.61)	0.2618	
	Other	3/ 67 (4.5)	2/ 80 (2.5)	1.79 (0.31, 10.41)	0.5162	
	COVID-19 vaccination status within six months prior to randomization					0.8923
	Yes	2/ 74 (2.7)	1/ 78 (1.3)	2.11 (0.20, 22.76)	0.5390	
	No	16/ 474 (3.4)	6/ 447 (1.3)	2.51 (0.99, 6.37)	0.0518	
	Prior SARS-CoV-2 infection within six months prior to randomization					NE
	Yes	0/ 24 (0.0)	0/ 27 (0.0)	NE		
	No	18/ 524 (3.4)	7/ 498 (1.4)	2.44 (1.03, 5.80)	0.0427	
	AZD7442 use within 12 months prior to randomization					0.8871
	Yes	1/ 100 (1.0)	0/ 98 (0.0)	2.94 (0.12, 71.32)	0.5073	
	No	17/ 448 (3.8)	7/ 427 (1.6)	2.31 (0.97, 5.53)	0.0587	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.9100
	Yes	2/ 94 (2.1)	1/ 101 (1.0)	2.15 (0.20, 23.31)	0.5294	
	No	16/ 454 (3.5)	6/ 424 (1.4)	2.49 (0.98, 6.30)	0.0542	
	Solid organ or stem cell transplants					0.7061
	Yes	9/ 268 (3.4)	3/ 263 (1.1)	2.94 (0.81, 10.75)	0.1023	
	No	9/ 280 (3.2)	4/ 262 (1.5)	2.11 (0.66, 6.75)	0.2107	
	Solid tumor cancer and on active treatment					0.9161
	Yes	2/ 18 (11.1)	1/ 20 (5.0)	2.22 (0.22, 22.49)	0.4989	
	No	16/ 530 (3.0)	6/ 505 (1.2)	2.54 (1.00, 6.44)	0.0495	
	Taking immunosuppressive medicines					0.8041
	Yes	15/ 491 (3.1)	6/ 464 (1.3)	2.36 (0.92, 6.04)	0.0725	
	No	3/ 57 (5.3)	1/ 61 (1.6)	3.21 (0.34, 29.98)	0.3062	
	Electrocardiogram (ECG) interpretation					0.0973
	Normal	11/ 328 (3.4)	2/ 332 (0.6)	5.57 (1.24, 24.92)	0.0248	
	Abnormal	6/ 184 (3.3)	5/ 171 (2.9)	1.12 (0.35, 3.59)	0.8549	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Blood and lymphatic system disorders	Body Mass Index					0.5142
	<30 kg/m2	12/ 348 (3.4)	6/ 368 (1.6)	2.11 (0.80, 5.57)	0.1297	
	>=30 kg/m2	6/ 198 (3.0)	1/ 151 (0.7)	4.58 (0.56, 37.61)	0.1571	
	Hematological malignancies					0.7186
	Yes	4/ 100 (4.0)	2/ 94 (2.1)	1.88 (0.35, 10.03)	0.4598	
	No	14/ 448 (3.1)	5/ 431 (1.2)	2.69 (0.98, 7.41)	0.0551	
	Moderate or severe secondary Immunodeficiency					0.9442
	Yes	1/ 23 (4.3)	0/ 20 (0.0)	2.63 (0.11, 61.05)	0.5477	
	No	17/ 525 (3.2)	7/ 505 (1.4)	2.34 (0.98, 5.59)	0.0564	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: General disorders and administration site conditions, PT: Fatigue	Age					0.1515
	< 65	17/ 360 (4.7)	23/ 352 (6.5)	0.72 (0.39, 1.33)	0.2963	
	>= 65	6/ 188 (3.2)	17/ 173 (9.8)	0.32 (0.13, 0.80)	0.0151	
	Sex					0.4156
	Male	13/ 249 (5.2)	29/ 274 (10.6)	0.49 (0.26, 0.93)	0.0282	
	Female	10/ 299 (3.3)	11/ 251 (4.4)	0.76 (0.33, 1.77)	0.5281	
	Region					0.6582
	US	11/ 323 (3.4)	12/ 272 (4.4)	0.77 (0.35, 1.72)	0.5270	
	Europe	8/ 158 (5.1)	17/ 173 (9.8)	0.52 (0.23, 1.16)	0.1096	
	Other	4/ 67 (6.0)	11/ 80 (13.8)	0.43 (0.14, 1.30)	0.1362	
	COVID-19 vaccination status within six months prior to randomization					0.9449
	Yes	3/ 74 (4.1)	6/ 78 (7.7)	0.53 (0.14, 2.03)	0.3520	
	No	20/ 474 (4.2)	34/ 447 (7.6)	0.55 (0.32, 0.95)	0.0315	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.7168
	Yes	2/ 24 (8.3)	3/ 27 (11.1)	0.75 (0.14, 4.12)	0.7405	
	No	21/ 524 (4.0)	37/ 498 (7.4)	0.54 (0.32, 0.91)	0.0203	
	AZD7442 use within 12 months prior to randomization					0.9382
	Yes	6/ 100 (6.0)	11/ 98 (11.2)	0.53 (0.21, 1.39)	0.1986	
	No	17/ 448 (3.8)	29/ 427 (6.8)	0.56 (0.31, 1.00)	0.0507	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.7800
	Yes	4/ 94 (4.3)	9/ 101 (8.9)	0.48 (0.15, 1.50)	0.2053	
	No	19/ 454 (4.2)	31/ 424 (7.3)	0.57 (0.33, 1.00)	0.0490	
	Solid organ or stem cell transplants					0.3194
	Yes	13/ 268 (4.9)	18/ 263 (6.8)	0.71 (0.35, 1.42)	0.3301	
	No	10/ 280 (3.6)	22/ 262 (8.4)	0.43 (0.21, 0.88)	0.0214	
	Solid tumor cancer and on active treatment					0.2556
	Yes	1/ 18 (5.6)	0/ 20 (0.0)	3.32 (0.14, 76.60)	0.4543	
	No	22/ 530 (4.2)	40/ 505 (7.9)	0.52 (0.32, 0.87)	0.0123	
	Taking immunosuppressive medicines					0.8192
	Yes	20/ 491 (4.1)	35/ 464 (7.5)	0.54 (0.32, 0.92)	0.0239	
	No	3/ 57 (5.3)	5/ 61 (8.2)	0.64 (0.16, 2.57)	0.5307	
	Electrocardiogram (ECG) interpretation					0.3342
	Normal	16/ 328 (4.9)	22/ 332 (6.6)	0.74 (0.39, 1.38)	0.3372	
	Abnormal	7/ 184 (3.8)	15/ 171 (8.8)	0.43 (0.18, 1.04)	0.0606	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: General disorders and administration site conditions, PT: Fatigue	Body Mass Index					0.6209
	<30 kg/m2	14/ 348 (4.0)	25/ 368 (6.8)	0.59 (0.31, 1.12)	0.1073	
	>=30 kg/m2	9/ 198 (4.5)	15/ 151 (9.9)	0.46 (0.21, 1.02)	0.0551	
	Hematological malignancies					0.8675
	Yes	6/ 100 (6.0)	11/ 94 (11.7)	0.51 (0.20, 1.33)	0.1700	
	No	17/ 448 (3.8)	29/ 431 (6.7)	0.56 (0.31, 1.01)	0.0545	
	Moderate or severe secondary Immunodeficiency					0.7371
	Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.87 (0.06, 13.02)	0.9194	
	No	22/ 525 (4.2)	39/ 505 (7.7)	0.54 (0.33, 0.90)	0.0184	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: COVID-19	Age					0.6588
	< 65	23/ 360 (6.4)	45/ 352 (12.8)	0.50 (0.31, 0.81)	0.0047	
	>= 65	10/ 188 (5.3)	15/ 173 (8.7)	0.61 (0.28, 1.33)	0.2154	
	Sex					0.4054
	Male	12/ 249 (4.8)	31/ 274 (11.3)	0.43 (0.22, 0.81)	0.0094	
	Female	21/ 299 (7.0)	29/ 251 (11.6)	0.61 (0.36, 1.04)	0.0687	
	Region					0.7776
	US	16/ 323 (5.0)	23/ 272 (8.5)	0.59 (0.32, 1.09)	0.0895	
	Europe	14/ 158 (8.9)	27/ 173 (15.6)	0.57 (0.31, 1.04)	0.0682	
	Other	3/ 67 (4.5)	10/ 80 (12.5)	0.36 (0.10, 1.25)	0.1071	
	COVID-19 vaccination status within six months prior to randomization					0.8345
	Yes	5/ 74 (6.8)	11/ 78 (14.1)	0.48 (0.17, 1.31)	0.1526	
	No	28/ 474 (5.9)	49/ 447 (11.0)	0.54 (0.34, 0.84)	0.0066	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.8277
	Yes	0/ 24 (0.0)	1/ 27 (3.7)	0.37 (0.02, 8.75)	0.5405	
	No	33/ 524 (6.3)	59/ 498 (11.8)	0.53 (0.35, 0.80)	0.0024	
	AZD7442 use within 12 months prior to randomization					0.8818
	Yes	5/ 100 (5.0)	10/ 98 (10.2)	0.49 (0.17, 1.38)	0.1775	
	No	28/ 448 (6.3)	50/ 427 (11.7)	0.53 (0.34, 0.83)	0.0055	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.7265
	Yes	5/ 94 (5.3)	12/ 101 (11.9)	0.45 (0.16, 1.22)	0.1170	
	No	28/ 454 (6.2)	48/ 424 (11.3)	0.54 (0.35, 0.85)	0.0077	
	Solid organ or stem cell transplants					0.1398
	Yes	19/ 268 (7.1)	26/ 263 (9.9)	0.72 (0.41, 1.26)	0.2501	
	No	14/ 280 (5.0)	34/ 262 (13.0)	0.39 (0.21, 0.70)	0.0018	
	Solid tumor cancer and on active treatment					0.2457
	Yes	1/ 18 (5.6)	0/ 20 (0.0)	3.32 (0.14, 76.60)	0.4543	
	No	32/ 530 (6.0)	60/ 505 (11.9)	0.51 (0.34, 0.77)	0.0013	
	Taking immunosuppressive medicines					0.7957
	Yes	31/ 491 (6.3)	55/ 464 (11.9)	0.53 (0.35, 0.81)	0.0034	
	No	2/ 57 (3.5)	5/ 61 (8.2)	0.43 (0.09, 2.12)	0.2985	
	Electrocardiogram (ECG) interpretation					0.1612
	Normal	22/ 328 (6.7)	47/ 332 (14.2)	0.47 (0.29, 0.77)	0.0024	
	Abnormal	11/ 184 (6.0)	11/ 171 (6.4)	0.93 (0.41, 2.09)	0.8592	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: COVID-19	Body Mass Index					0.5705
	<30 kg/m2	21/ 348 (6.0)	44/ 368 (12.0)	0.50 (0.31, 0.83)	0.0072	
	>=30 kg/m2	12/ 198 (6.1)	14/ 151 (9.3)	0.65 (0.31, 1.37)	0.2611	
	Hematological malignancies					0.7592
	Yes	7/ 100 (7.0)	11/ 94 (11.7)	0.60 (0.24, 1.48)	0.2657	
	No	26/ 448 (5.8)	49/ 431 (11.4)	0.51 (0.32, 0.81)	0.0039	
	Moderate or severe secondary Immunodeficiency					0.7145
	Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.87 (0.06, 13.02)	0.9194	
	No	32/ 525 (6.1)	59/ 505 (11.7)	0.52 (0.35, 0.79)	0.0020	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: Influenza	Age					
	< 65	3/ 360 (0.8)	3/ 352 (0.9)			
	>= 65	9/ 188 (4.8)	0/ 173 (0.0)			
	Sex					0.2627
	Male	5/ 249 (2.0)	0/ 274 (0.0)	12.10 (0.67, 217.72)	0.0909	
	Female	7/ 299 (2.3)	3/ 251 (1.2)	1.96 (0.51, 7.50)	0.3262	
	Region					
	US	4/ 323 (1.2)	2/ 272 (0.7)			
	Europe	7/ 158 (4.4)	1/ 173 (0.6)			
	Other	1/ 67 (1.5)	0/ 80 (0.0)			
	COVID-19 vaccination status within six months prior to randomization					0.1213
	Yes	0/ 74 (0.0)	1/ 78 (1.3)	0.35 (0.01, 8.49)	0.5195	
	No	12/ 474 (2.5)	2/ 447 (0.4)	5.66 (1.27, 25.14)	0.0227	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.9832
	Yes	1/ 24 (4.2)	0/ 27 (0.0)	3.36 (0.14, 78.79)	0.4515	
	No	11/ 524 (2.1)	3/ 498 (0.6)	3.48 (0.98, 12.42)	0.0542	
	AZD7442 use within 12 months prior to randomization					0.7852
	Yes	3/ 100 (3.0)	1/ 98 (1.0)	2.94 (0.31, 27.78)	0.3467	
	No	9/ 448 (2.0)	2/ 427 (0.5)	4.29 (0.93, 19.74)	0.0615	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.3287
	Yes	1/ 94 (1.1)	1/ 101 (1.0)	1.07 (0.07, 16.93)	0.9593	
	No	11/ 454 (2.4)	2/ 424 (0.5)	5.14 (1.15, 23.04)	0.0326	
	Solid organ or stem cell transplants					0.9722
	Yes	4/ 268 (1.5)	1/ 263 (0.4)	3.93 (0.44, 34.89)	0.2199	
	No	8/ 280 (2.9)	2/ 262 (0.8)	3.74 (0.80, 17.46)	0.0931	
	Solid tumor cancer and on active treatment					NE
	Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
	No	12/ 530 (2.3)	3/ 505 (0.6)	3.81 (1.08, 13.43)	0.0373	
	Taking immunosuppressive medicines					0.4099
	Yes	8/ 491 (1.6)	3/ 464 (0.6)	2.52 (0.67, 9.44)	0.1702	
	No	4/ 57 (7.0)	0/ 61 (0.0)	9.62 (0.53, 174.80)	0.1260	
	Electrocardiogram (ECG) interpretation					
	Normal	7/ 328 (2.1)	2/ 332 (0.6)			
	Abnormal	4/ 184 (2.2)	1/ 171 (0.6)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: Influenza	Body Mass Index					0.7728
	<30 kg/m2	8/ 348 (2.3)	2/ 368 (0.5)	4.23 (0.90, 19.78)	0.0669	
	>=30 kg/m2	4/ 198 (2.0)	0/ 151 (0.0)	6.87 (0.37, 126.71)	0.1948	
	Hematological malignancies					
	Yes	6/ 100 (6.0)	0/ 94 (0.0)			
	No	6/ 448 (1.3)	3/ 431 (0.7)			
	Moderate or severe secondary Immunodeficiency					NE
	Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
	No	12/ 525 (2.3)	3/ 505 (0.6)	3.85 (1.09, 13.55)	0.0360	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Age					0.3969
	< 65	19/ 360 (5.3)	7/ 352 (2.0)	2.65 (1.13, 6.23)	0.0251	
	>= 65	6/ 188 (3.2)	4/ 173 (2.3)	1.38 (0.40, 4.81)	0.6128	
	Sex					0.7758
	Male	13/ 249 (5.2)	7/ 274 (2.6)	2.04 (0.83, 5.04)	0.1207	
	Female	12/ 299 (4.0)	4/ 251 (1.6)	2.52 (0.82, 7.71)	0.1057	
	Region					0.5188
	US	13/ 323 (4.0)	7/ 272 (2.6)	1.56 (0.63, 3.86)	0.3326	
	Europe	8/ 158 (5.1)	2/ 173 (1.2)	4.38 (0.94, 20.32)	0.0592	
	Other	4/ 67 (6.0)	2/ 80 (2.5)	2.39 (0.45, 12.64)	0.3058	
	COVID-19 vaccination status within six months prior to randomization					0.7002
	Yes	3/ 74 (4.1)	2/ 78 (2.6)	1.58 (0.27, 9.20)	0.6101	
	No	22/ 474 (4.6)	9/ 447 (2.0)	2.31 (1.07, 4.95)	0.0323	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.3545
	Yes	3/ 24 (12.5)	0/ 27 (0.0)	7.84 (0.43, 144.45)	0.1660	
	No	22/ 524 (4.2)	11/ 498 (2.2)	1.90 (0.93, 3.88)	0.0776	
	AZD7442 use within 12 months prior to randomization					0.1040
	Yes	3/ 100 (3.0)	4/ 98 (4.1)	0.73 (0.17, 3.20)	0.6816	
	No	22/ 448 (4.9)	7/ 427 (1.6)	3.00 (1.29, 6.94)	0.0105	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.7778
	Yes	5/ 94 (5.3)	2/ 101 (2.0)	2.69 (0.53, 13.51)	0.2306	
	No	20/ 454 (4.4)	9/ 424 (2.1)	2.08 (0.96, 4.51)	0.0650	
	Solid organ or stem cell transplants					0.1537
	Yes	13/ 268 (4.9)	3/ 263 (1.1)	4.25 (1.23, 14.75)	0.0226	
	No	12/ 280 (4.3)	8/ 262 (3.1)	1.40 (0.58, 3.38)	0.4495	
	Solid tumor cancer and on active treatment					NE
	Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
	No	25/ 530 (4.7)	11/ 505 (2.2)	2.17 (1.08, 4.35)	0.0302	
	Taking immunosuppressive medicines					0.2721
	Yes	21/ 491 (4.3)	11/ 464 (2.4)	1.80 (0.88, 3.70)	0.1074	
	No	4/ 57 (7.0)	0/ 61 (0.0)	9.62 (0.53, 174.80)	0.1260	
	Electrocardiogram (ECG) interpretation					0.9169
	Normal	16/ 328 (4.9)	6/ 332 (1.8)	2.70 (1.07, 6.81)	0.0355	
	Abnormal	8/ 184 (4.3)	3/ 171 (1.8)	2.48 (0.67, 9.19)	0.1747	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Body Mass Index					0.3195
	<30 kg/m2	16/ 348 (4.6)	6/ 368 (1.6)	2.82 (1.12, 7.12)	0.0283	
	>=30 kg/m2	9/ 198 (4.5)	5/ 151 (3.3)	1.37 (0.47, 4.01)	0.5626	
	Hematological malignancies					0.8504
	Yes	4/ 100 (4.0)	2/ 94 (2.1)	1.88 (0.35, 10.03)	0.4598	
	No	21/ 448 (4.7)	9/ 431 (2.1)	2.24 (1.04, 4.85)	0.0395	
	Moderate or severe secondary Immunodeficiency					0.8918
	Yes	1/ 23 (4.3)	0/ 20 (0.0)	2.63 (0.11, 61.05)	0.5477	
	No	24/ 525 (4.6)	11/ 505 (2.2)	2.10 (1.04, 4.24)	0.0388	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	27 (4.9)	22 (4.2)
	Number of censored subjects, n (%)	521 (95.1)	503 (95.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.18 (0.68, 2.04)	
	p-value	0.5640	
	Odds Ratio (95% CI) [1]	1.18 (0.67, 2.11)	
	p-value	0.5639	
	Risk Difference (95% CI) [1]	0.74 (-1.76, 3.23)	
	p-value	0.5628	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 1: Up to Day 91 visit 4 after first study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	24 (4.4)	19 (3.6)
	Number of censored subjects, n (%)	524 (95.6)	506 (96.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.21 (0.67, 2.18)	
	p-value	0.5262	
	Odds Ratio (95% CI) [1]	1.22 (0.66, 2.25)	
	p-value	0.5261	
	Risk Difference (95% CI) [1]	0.76 (-1.58, 3.10)	
	p-value	0.5246	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including 103 days following the first dosing date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	19 (3.5)	10 (1.9)
	Number of censored subjects, n (%)	529 (96.5)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.82 (0.85, 3.88)	
	p-value	0.1206	
	Odds Ratio (95% CI) [1]	1.85 (0.85, 4.02)	
	p-value	0.1200	
	Risk Difference (95% CI) [1]	1.56 (-0.36, 3.49)	
	p-value	0.1120	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Cardiac disorders	Number of subjects with events, n (%)	13 (2.4)	16 (3.0)
	Number of censored subjects, n (%)	535 (97.6)	509 (97.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.78 (0.38, 1.60)	
	p-value	0.4965	
	Odds Ratio (95% CI) [1]	0.77 (0.37, 1.62)	
	p-value	0.4964	
	Risk Difference (95% CI) [1]	-0.68 (-2.62, 1.27)	
	p-value	0.4963	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	6 (1.1)	13 (2.5)
	Number of censored subjects, n (%)	542 (98.9)	512 (97.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.44 (0.17, 1.15)	
	p-value	0.0957	
	Odds Ratio (95% CI) [1]	0.44 (0.16, 1.16)	
	p-value	0.0951	
	Risk Difference (95% CI) [1]	-1.38 (-2.97, 0.21)	
	p-value	0.0885	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Eye disorders	Number of subjects with events, n (%)	11 (2.0)	7 (1.3)
	Number of censored subjects, n (%)	537 (98.0)	518 (98.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.51 (0.59, 3.85)	
	p-value	0.3937	
	Odds Ratio (95% CI) [1]	1.52 (0.58, 3.94)	
	p-value	0.3934	
	Risk Difference (95% CI) [1]	0.67 (-0.86, 2.20)	
	p-value	0.3880	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	71 (13.0)	70 (13.3)
	Number of censored subjects, n (%)	477 (87.0)	455 (86.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.97 (0.71, 1.32)	
	p-value	0.8550	
	Odds Ratio (95% CI) [1]	0.97 (0.68, 1.38)	
	p-value	0.8550	
	Risk Difference (95% CI) [1]	-0.38 (-4.42, 3.67)	
	p-value	0.8550	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	24 (4.4)	33 (6.3)
	Number of censored subjects, n (%)	524 (95.6)	492 (93.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.70 (0.42, 1.16)	
	p-value	0.1666	
	Odds Ratio (95% CI) [1]	0.68 (0.40, 1.17)	
	p-value	0.1662	
	Risk Difference (95% CI) [1]	-1.91 (-4.60, 0.79)	
	p-value	0.1652	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	13 (2.4)	16 (3.0)
	Number of censored subjects, n (%)	535 (97.6)	509 (97.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.78 (0.38, 1.60)	
	p-value	0.4965	
	Odds Ratio (95% CI) [1]	0.77 (0.37, 1.62)	
	p-value	0.4964	
	Risk Difference (95% CI) [1]	-0.68 (-2.62, 1.27)	
	p-value	0.4963	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	95 (17.3)	109 (20.8)
	Number of censored subjects, n (%)	453 (82.7)	416 (79.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.83 (0.65, 1.07)	
	p-value	0.1536	
	Odds Ratio (95% CI) [1]	0.80 (0.59, 1.09)	
	p-value	0.1533	
	Risk Difference (95% CI) [1]	-3.43 (-8.13, 1.27)	
	p-value	0.1530	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Asthenia	Number of subjects with events, n (%)	17 (3.1)	17 (3.2)
	Number of censored subjects, n (%)	531 (96.9)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.49, 1.86)	
	p-value	0.8989	
	Odds Ratio (95% CI) [1]	0.96 (0.48, 1.89)	
	p-value	0.8989	
	Risk Difference (95% CI) [1]	-0.14 (-2.23, 1.96)	
	p-value	0.8989	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	25 (4.6)	42 (8.0)
	Number of censored subjects, n (%)	523 (95.4)	483 (92.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.57 (0.35, 0.92)	
	p-value	0.0219	
	Odds Ratio (95% CI) [1]	0.55 (0.33, 0.92)	
	p-value	0.0216	
	Risk Difference (95% CI) [1]	-3.44 (-6.34, -0.53)	
	p-value	0.0204	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Injection site pain	Number of subjects with events, n (%)	8 (1.5)	11 (2.1)
	Number of censored subjects, n (%)	540 (98.5)	514 (97.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.70 (0.28, 1.72)	
	p-value	0.4328	
	Odds Ratio (95% CI) [1]	0.69 (0.28, 1.73)	
	p-value	0.4326	
	Risk Difference (95% CI) [1]	-0.64 (-2.22, 0.95)	
	p-value	0.4318	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	20 (3.6)	18 (3.4)
	Number of censored subjects, n (%)	528 (96.4)	507 (96.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.06 (0.57, 1.99)	
	p-value	0.8448	
	Odds Ratio (95% CI) [1]	1.07 (0.56, 2.04)	
	p-value	0.8448	
	Risk Difference (95% CI) [1]	0.22 (-1.99, 2.43)	
	p-value	0.8446	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	215 (39.2)	195 (37.1)
	Number of censored subjects, n (%)	333 (60.8)	330 (62.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.06 (0.91, 1.23)	
	p-value	0.4814	
	Odds Ratio (95% CI) [1]	1.09 (0.85, 1.40)	
	p-value	0.4811	
	Risk Difference (95% CI) [1]	2.09 (-3.72, 7.90)	
	p-value	0.4809	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	11 (2.0)	7 (1.3)
	Number of censored subjects, n (%)	537 (98.0)	518 (98.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.51 (0.59, 3.85)	
	p-value	0.3937	
	Odds Ratio (95% CI) [1]	1.52 (0.58, 3.94)	
	p-value	0.3934	
	Risk Difference (95% CI) [1]	0.67 (-0.86, 2.20)	
	p-value	0.3880	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: COVID-19	Number of subjects with events, n (%)	53 (9.7)	79 (15.0)
	Number of censored subjects, n (%)	495 (90.3)	446 (85.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.64 (0.46, 0.89)	
	p-value	0.0080	
	Odds Ratio (95% CI) [1]	0.60 (0.42, 0.88)	
	p-value	0.0078	
	Risk Difference (95% CI) [1]	-5.38 (-9.31, -1.44)	
	p-value	0.0074	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Influenza	Number of subjects with events, n (%)	17 (3.1)	7 (1.3)
	Number of censored subjects, n (%)	531 (96.9)	518 (98.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.33 (0.97, 5.56)	
	p-value	0.0577	
	Odds Ratio (95% CI) [1]	2.37 (0.97, 5.76)	
	p-value	0.0571	
	Risk Difference (95% CI) [1]	1.77 (0.02, 3.52)	
	p-value	0.0478	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	18 (3.3)	14 (2.7)
	Number of censored subjects, n (%)	530 (96.7)	511 (97.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.23 (0.62, 2.45)	
	p-value	0.5527	
	Odds Ratio (95% CI) [1]	1.24 (0.61, 2.52)	
	p-value	0.5526	
	Risk Difference (95% CI) [1]	0.62 (-1.41, 2.65)	
	p-value	0.5510	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	13 (2.4)	9 (1.7)
	Number of censored subjects, n (%)	535 (97.6)	516 (98.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.38 (0.60, 3.21)	
	p-value	0.4492	
	Odds Ratio (95% CI) [1]	1.39 (0.59, 3.29)	
	p-value	0.4490	
	Risk Difference (95% CI) [1]	0.66 (-1.03, 2.35)	
	p-value	0.4454	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Rhinitis	Number of subjects with events, n (%)	8 (1.5)	10 (1.9)
	Number of censored subjects, n (%)	540 (98.5)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.77 (0.30, 1.93)	
	p-value	0.5717	
	Odds Ratio (95% CI) [1]	0.76 (0.30, 1.95)	
	p-value	0.5717	
	Risk Difference (95% CI) [1]	-0.44 (-1.99, 1.10)	
	p-value	0.5716	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	33 (6.0)	21 (4.0)
	Number of censored subjects, n (%)	515 (94.0)	504 (96.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.51 (0.88, 2.57)	
	p-value	0.1331	
	Odds Ratio (95% CI) [1]	1.54 (0.88, 2.69)	
	p-value	0.1325	
	Risk Difference (95% CI) [1]	2.02 (-0.58, 4.63)	
	p-value	0.1279	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	27 (4.9)	27 (5.1)
	Number of censored subjects, n (%)	521 (95.1)	498 (94.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.57, 1.61)	
	p-value	0.8716	
	Odds Ratio (95% CI) [1]	0.96 (0.55, 1.65)	
	p-value	0.8716	
	Risk Difference (95% CI) [1]	-0.22 (-2.83, 2.40)	
	p-value	0.8716	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	36 (6.6)	40 (7.6)
	Number of censored subjects, n (%)	512 (93.4)	485 (92.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.86 (0.56, 1.33)	
	p-value	0.5033	
	Odds Ratio (95% CI) [1]	0.85 (0.53, 1.36)	
	p-value	0.5032	
	Risk Difference (95% CI) [1]	-1.05 (-4.12, 2.02)	
	p-value	0.5034	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Investigations	Number of subjects with events, n (%)	17 (3.1)	12 (2.3)
	Number of censored subjects, n (%)	531 (96.9)	513 (97.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.36 (0.65, 2.81)	
	p-value	0.4117	
	Odds Ratio (95% CI) [1]	1.37 (0.65, 2.89)	
	p-value	0.4115	
	Risk Difference (95% CI) [1]	0.82 (-1.12, 2.75)	
	p-value	0.4081	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	28 (5.1)	25 (4.8)
	Number of censored subjects, n (%)	520 (94.9)	500 (95.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.07 (0.63, 1.82)	
	p-value	0.7929	
	Odds Ratio (95% CI) [1]	1.08 (0.62, 1.87)	
	p-value	0.7929	
	Risk Difference (95% CI) [1]	0.35 (-2.24, 2.94)	
	p-value	0.7927	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	54 (9.9)	55 (10.5)
	Number of censored subjects, n (%)	494 (90.1)	470 (89.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.94 (0.66, 1.34)	
	p-value	0.7360	
	Odds Ratio (95% CI) [1]	0.93 (0.63, 1.39)	
	p-value	0.7360	
	Risk Difference (95% CI) [1]	-0.62 (-4.24, 3.00)	
	p-value	0.7361	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia	Number of subjects with events, n (%)	11 (2.0)	20 (3.8)
	Number of censored subjects, n (%)	537 (98.0)	505 (96.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.53 (0.25, 1.09)	
	p-value	0.0836	
	Odds Ratio (95% CI) [1]	0.52 (0.25, 1.09)	
	p-value	0.0831	
	Risk Difference (95% CI) [1]	-1.80 (-3.82, 0.21)	
	p-value	0.0796	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	19 (3.5)	10 (1.9)
	Number of censored subjects, n (%)	529 (96.5)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.82 (0.85, 3.88)	
	p-value	0.1206	
	Odds Ratio (95% CI) [1]	1.85 (0.85, 4.02)	
	p-value	0.1200	
	Risk Difference (95% CI) [1]	1.56 (-0.36, 3.49)	
	p-value	0.1120	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Nervous system disorders	Number of subjects with events, n (%)	61 (11.1)	61 (11.6)
	Number of censored subjects, n (%)	487 (88.9)	464 (88.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.69, 1.34)	
	p-value	0.8014	
	Odds Ratio (95% CI) [1]	0.95 (0.65, 1.39)	
	p-value	0.8014	
	Risk Difference (95% CI) [1]	-0.49 (-4.29, 3.31)	
	p-value	0.8015	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	36 (6.6)	38 (7.2)
	Number of censored subjects, n (%)	512 (93.4)	487 (92.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.91 (0.58, 1.41)	
	p-value	0.6658	
	Odds Ratio (95% CI) [1]	0.90 (0.56, 1.45)	
	p-value	0.6657	
	Risk Difference (95% CI) [1]	-0.67 (-3.70, 2.37)	
	p-value	0.6659	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	10 (1.8)	9 (1.7)
	Number of censored subjects, n (%)	538 (98.2)	516 (98.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.06 (0.44, 2.60)	
	p-value	0.8909	
	Odds Ratio (95% CI) [1]	1.07 (0.43, 2.64)	
	p-value	0.8909	
	Risk Difference (95% CI) [1]	0.11 (-1.47, 1.69)	
	p-value	0.8908	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	17 (3.1)	17 (3.2)
	Number of censored subjects, n (%)	531 (96.9)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.49, 1.86)	
	p-value	0.8989	
	Odds Ratio (95% CI) [1]	0.96 (0.48, 1.89)	
	p-value	0.8989	
	Risk Difference (95% CI) [1]	-0.14 (-2.23, 1.96)	
	p-value	0.8989	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	116 (21.2)	99 (18.9)
	Number of censored subjects, n (%)	432 (78.8)	426 (81.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.12 (0.88, 1.43)	
	p-value	0.3451	
	Odds Ratio (95% CI) [1]	1.16 (0.86, 1.56)	
	p-value	0.3447	
	Risk Difference (95% CI) [1]	2.31 (-2.47, 7.10)	
	p-value	0.3439	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	50 (9.1)	50 (9.5)
	Number of censored subjects, n (%)	498 (90.9)	475 (90.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.66, 1.39)	
	p-value	0.8219	
	Odds Ratio (95% CI) [1]	0.95 (0.63, 1.44)	
	p-value	0.8219	
	Risk Difference (95% CI) [1]	-0.40 (-3.88, 3.08)	
	p-value	0.8219	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Number of subjects with events, n (%)	13 (2.4)	4 (0.8)
	Number of censored subjects, n (%)	535 (97.6)	521 (99.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	3.11 (1.02, 9.49)	
	p-value	0.0457	
	Odds Ratio (95% CI) [1]	3.16 (1.03, 9.77)	
	p-value	0.0451	
	Risk Difference (95% CI) [1]	1.61 (0.13, 3.09)	
	p-value	0.0324	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Number of subjects with events, n (%)	26 (4.7)	13 (2.5)
	Number of censored subjects, n (%)	522 (95.3)	512 (97.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (1.00, 3.69)	
	p-value	0.0516	
	Odds Ratio (95% CI) [1]	1.96 (1.00, 3.86)	
	p-value	0.0510	
	Risk Difference (95% CI) [1]	2.27 (0.05, 4.49)	
	p-value	0.0454	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Number of subjects with events, n (%)	31 (5.7)	19 (3.6)
	Number of censored subjects, n (%)	517 (94.3)	506 (96.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.56 (0.89, 2.73)	
	p-value	0.1169	
	Odds Ratio (95% CI) [1]	1.60 (0.89, 2.86)	
	p-value	0.1163	
	Risk Difference (95% CI) [1]	2.04 (-0.47, 4.55)	
	p-value	0.1114	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Rhinorrhoea	Number of subjects with events, n (%)	32 (5.8)	33 (6.3)
	Number of censored subjects, n (%)	516 (94.2)	492 (93.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.93 (0.58, 1.49)	
	p-value	0.7594	
	Odds Ratio (95% CI) [1]	0.92 (0.56, 1.53)	
	p-value	0.7594	
	Risk Difference (95% CI) [1]	-0.45 (-3.30, 2.41)	
	p-value	0.7595	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	25 (4.6)	17 (3.2)
	Number of censored subjects, n (%)	523 (95.4)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.41 (0.77, 2.58)	
	p-value	0.2663	
	Odds Ratio (95% CI) [1]	1.43 (0.76, 2.68)	
	p-value	0.2659	
	Risk Difference (95% CI) [1]	1.32 (-0.99, 3.64)	
	p-value	0.2617	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Vascular disorders	Number of subjects with events, n (%)	27 (4.9)	20 (3.8)
	Number of censored subjects, n (%)	521 (95.1)	505 (96.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.29 (0.73, 2.28)	
	p-value	0.3728	
	Odds Ratio (95% CI) [1]	1.31 (0.72, 2.36)	
	p-value	0.3725	
	Risk Difference (95% CI) [1]	1.12 (-1.32, 3.56)	
	p-value	0.3698	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	9 (1.6)	12 (2.3)
	Number of censored subjects, n (%)	539 (98.4)	513 (97.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.72 (0.31, 1.69)	
	p-value	0.4491	
	Odds Ratio (95% CI) [1]	0.71 (0.30, 1.71)	
	p-value	0.4490	
	Risk Difference (95% CI) [1]	-0.64 (-2.31, 1.02)	
	p-value	0.4484	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: General disorders and administration site conditions, PT: Fatigue	Age					0.1316
	< 65	19/ 360 (5.3)	25/ 352 (7.1)	0.74 (0.42, 1.32)	0.3142	
	>= 65	6/ 188 (3.2)	17/ 173 (9.8)	0.32 (0.13, 0.80)	0.0151	
	Sex					0.6429
	Male	15/ 249 (6.0)	30/ 274 (10.9)	0.55 (0.30, 1.00)	0.0493	
	Female	10/ 299 (3.3)	12/ 251 (4.8)	0.70 (0.31, 1.59)	0.3944	
	Region					0.5165
	US	12/ 323 (3.7)	12/ 272 (4.4)	0.84 (0.38, 1.84)	0.6674	
	Europe	9/ 158 (5.7)	18/ 173 (10.4)	0.55 (0.25, 1.18)	0.1254	
	Other	4/ 67 (6.0)	12/ 80 (15.0)	0.40 (0.13, 1.18)	0.0958	
	COVID-19 vaccination status within six months prior to randomization					0.9034
	Yes	3/ 74 (4.1)	6/ 78 (7.7)	0.53 (0.14, 2.03)	0.3520	
	No	22/ 474 (4.6)	36/ 447 (8.1)	0.58 (0.34, 0.96)	0.0357	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.7477
	Yes	2/ 24 (8.3)	3/ 27 (11.1)	0.75 (0.14, 4.12)	0.7405	
	No	23/ 524 (4.4)	39/ 498 (7.8)	0.56 (0.34, 0.92)	0.0234	
	AZD7442 use within 12 months prior to randomization					0.9995
	Yes	7/ 100 (7.0)	12/ 98 (12.2)	0.57 (0.23, 1.39)	0.2179	
	No	18/ 448 (4.0)	30/ 427 (7.0)	0.57 (0.32, 1.01)	0.0543	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.7338
	Yes	4/ 94 (4.3)	9/ 101 (8.9)	0.48 (0.15, 1.50)	0.2053	
	No	21/ 454 (4.6)	33/ 424 (7.8)	0.59 (0.35, 1.01)	0.0547	
	Solid organ or stem cell transplants					0.3309
	Yes	14/ 268 (5.2)	19/ 263 (7.2)	0.72 (0.37, 1.41)	0.3422	
	No	11/ 280 (3.9)	23/ 262 (8.8)	0.45 (0.22, 0.90)	0.0241	
	Solid tumor cancer and on active treatment					0.1247
	Yes	2/ 18 (11.1)	0/ 20 (0.0)	5.53 (0.28, 107.96)	0.2596	
	No	23/ 530 (4.3)	42/ 505 (8.3)	0.52 (0.32, 0.85)	0.0098	
	Taking immunosuppressive medicines					0.7019
	Yes	21/ 491 (4.3)	36/ 464 (7.8)	0.55 (0.33, 0.93)	0.0256	
	No	4/ 57 (7.0)	6/ 61 (9.8)	0.71 (0.21, 2.40)	0.5852	
	Electrocardiogram (ECG) interpretation					0.3615
	Normal	17/ 328 (5.2)	23/ 332 (6.9)	0.75 (0.41, 1.37)	0.3496	
	Abnormal	8/ 184 (4.3)	16/ 171 (9.4)	0.46 (0.20, 1.06)	0.0679	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: General disorders and administration site conditions, PT: Fatigue	Body Mass Index					0.4113
	<30 kg/m2	16/ 348 (4.6)	26/ 368 (7.1)	0.65 (0.36, 1.19)	0.1642	
	>=30 kg/m2	9/ 198 (4.5)	16/ 151 (10.6)	0.43 (0.19, 0.94)	0.0355	
	Hematological malignancies					0.8040
	Yes	6/ 100 (6.0)	11/ 94 (11.7)	0.51 (0.20, 1.33)	0.1700	
	No	19/ 448 (4.2)	31/ 431 (7.2)	0.59 (0.34, 1.03)	0.0624	
	Moderate or severe secondary Immunodeficiency					0.8152
	Yes	1/ 23 (4.3)	2/ 20 (10.0)	0.43 (0.04, 4.44)	0.4825	
	No	24/ 525 (4.6)	40/ 505 (7.9)	0.58 (0.35, 0.94)	0.0283	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: COVID-19	Age					0.6038
	< 65	39/ 360 (10.8)	56/ 352 (15.9)	0.68 (0.46, 1.00)	0.0483	
	>= 65	14/ 188 (7.4)	23/ 173 (13.3)	0.56 (0.30, 1.05)	0.0720	
	Sex					0.3329
	Male	21/ 249 (8.4)	43/ 274 (15.7)	0.54 (0.33, 0.88)	0.0135	
	Female	32/ 299 (10.7)	36/ 251 (14.3)	0.75 (0.48, 1.17)	0.1979	
	Region					0.6183
	US	29/ 323 (9.0)	34/ 272 (12.5)	0.72 (0.45, 1.15)	0.1662	
	Europe	20/ 158 (12.7)	33/ 173 (19.1)	0.66 (0.40, 1.11)	0.1163	
	Other	4/ 67 (6.0)	12/ 80 (15.0)	0.40 (0.13, 1.18)	0.0958	
	COVID-19 vaccination status within six months prior to randomization					0.3106
	Yes	6/ 74 (8.1)	15/ 78 (19.2)	0.42 (0.17, 1.03)	0.0577	
	No	47/ 474 (9.9)	64/ 447 (14.3)	0.69 (0.49, 0.99)	0.0417	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.1935
	Yes	0/ 24 (0.0)	5/ 27 (18.5)	0.10 (0.01, 1.75)	0.1154	
	No	53/ 524 (10.1)	74/ 498 (14.9)	0.68 (0.49, 0.95)	0.0226	
	AZD7442 use within 12 months prior to randomization					0.8861
	Yes	10/ 100 (10.0)	16/ 98 (16.3)	0.61 (0.29, 1.28)	0.1938	
	No	43/ 448 (9.6)	63/ 427 (14.8)	0.65 (0.45, 0.94)	0.0207	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.0810
	Yes	6/ 94 (6.4)	20/ 101 (19.8)	0.32 (0.14, 0.77)	0.0106	
	No	47/ 454 (10.4)	59/ 424 (13.9)	0.74 (0.52, 1.07)	0.1070	
	Solid organ or stem cell transplants					0.1651
	Yes	29/ 268 (10.8)	35/ 263 (13.3)	0.81 (0.51, 1.29)	0.3799	
	No	24/ 280 (8.6)	44/ 262 (16.8)	0.51 (0.32, 0.81)	0.0048	
	Solid tumor cancer and on active treatment					0.3012
	Yes	1/ 18 (5.6)	0/ 20 (0.0)	3.32 (0.14, 76.60)	0.4543	
	No	52/ 530 (9.8)	79/ 505 (15.6)	0.63 (0.45, 0.87)	0.0053	
	Taking immunosuppressive medicines					0.3267
	Yes	51/ 491 (10.4)	72/ 464 (15.5)	0.67 (0.48, 0.94)	0.0190	
	No	2/ 57 (3.5)	7/ 61 (11.5)	0.31 (0.07, 1.41)	0.1289	
	Electrocardiogram (ECG) interpretation					0.7383
	Normal	37/ 328 (11.3)	58/ 332 (17.5)	0.65 (0.44, 0.95)	0.0252	
	Abnormal	15/ 184 (8.2)	19/ 171 (11.1)	0.73 (0.39, 1.40)	0.3461	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: COVID-19	Body Mass Index					0.0369
	<30 kg/m2	29/ 348 (8.3)	61/ 368 (16.6)	0.50 (0.33, 0.76)	0.0012	
	>=30 kg/m2	23/ 198 (11.6)	16/ 151 (10.6)	1.10 (0.60, 2.00)	0.7647	
	Hematological malignancies					0.2513
	Yes	7/ 100 (7.0)	16/ 94 (17.0)	0.41 (0.18, 0.95)	0.0387	
	No	46/ 448 (10.3)	63/ 431 (14.6)	0.70 (0.49, 1.00)	0.0521	
	Moderate or severe secondary Immunodeficiency					0.8267
	Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.87 (0.06, 13.02)	0.9194	
	No	52/ 525 (9.9)	78/ 505 (15.4)	0.64 (0.46, 0.89)	0.0081	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
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NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Age					0.1282
	< 65	9/ 360 (2.5)	1/ 352 (0.3)	8.80 (1.12, 69.10)	0.0386	
	>= 65	4/ 188 (2.1)	3/ 173 (1.7)	1.23 (0.28, 5.40)	0.7869	
	Sex					0.6415
	Male	4/ 249 (1.6)	2/ 274 (0.7)	2.20 (0.41, 11.91)	0.3599	
	Female	9/ 299 (3.0)	2/ 251 (0.8)	3.78 (0.82, 17.32)	0.0872	
	Region					0.8560
	US	8/ 323 (2.5)	2/ 272 (0.7)	3.37 (0.72, 15.73)	0.1225	
	Europe	5/ 158 (3.2)	2/ 173 (1.2)	2.74 (0.54, 13.91)	0.2247	
	Other	0/ 67 (0.0)	0/ 80 (0.0)	NE		
	COVID-19 vaccination status within six months prior to randomization					0.6670
	Yes	2/ 74 (2.7)	0/ 78 (0.0)	5.27 (0.26, 107.91)	0.2809	
	No	11/ 474 (2.3)	4/ 447 (0.9)	2.59 (0.83, 8.08)	0.1005	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.9234
	Yes	1/ 24 (4.2)	0/ 27 (0.0)	3.36 (0.14, 78.79)	0.4515	
	No	12/ 524 (2.3)	4/ 498 (0.8)	2.85 (0.93, 8.78)	0.0679	
	AZD7442 use within 12 months prior to randomization					0.1802
	Yes	2/ 100 (2.0)	2/ 98 (2.0)	0.98 (0.14, 6.82)	0.9837	
	No	11/ 448 (2.5)	2/ 427 (0.5)	5.24 (1.17, 23.51)	0.0305	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.6546
	Yes	2/ 94 (2.1)	0/ 101 (0.0)	5.37 (0.26, 110.39)	0.2760	
	No	11/ 454 (2.4)	4/ 424 (0.9)	2.57 (0.82, 8.00)	0.1039	
	Solid organ or stem cell transplants					0.6511
	Yes	8/ 268 (3.0)	2/ 263 (0.8)	3.93 (0.84, 18.31)	0.0818	
	No	5/ 280 (1.8)	2/ 262 (0.8)	2.34 (0.46, 11.95)	0.3072	
	Solid tumor cancer and on active treatment					0.9305
	Yes	1/ 18 (5.6)	0/ 20 (0.0)	3.32 (0.14, 76.60)	0.4543	
	No	12/ 530 (2.3)	4/ 505 (0.8)	2.86 (0.93, 8.80)	0.0673	
	Taking immunosuppressive medicines					0.6610
	Yes	11/ 491 (2.2)	4/ 464 (0.9)	2.60 (0.83, 8.10)	0.0998	
	No	2/ 57 (3.5)	0/ 61 (0.0)	5.34 (0.26, 109.00)	0.2759	
	Electrocardiogram (ECG) interpretation					0.1521
	Normal	10/ 328 (3.0)	1/ 332 (0.3)	10.12 (1.30, 78.62)	0.0269	
	Abnormal	3/ 184 (1.6)	2/ 171 (1.2)	1.39 (0.24, 8.24)	0.7141	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
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Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

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D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 2: From first to second study intervention dose - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Body Mass Index					0.0842
	<30 kg/m2	9/ 348 (2.6)	1/ 368 (0.3)	9.52 (1.21, 74.73)	0.0321	
	>=30 kg/m2	4/ 198 (2.0)	3/ 151 (2.0)	1.02 (0.23, 4.48)	0.9824	
	Hematological malignancies					0.3939
	Yes	4/ 100 (4.0)	0/ 94 (0.0)	8.47 (0.46, 155.13)	0.1500	
	No	9/ 448 (2.0)	4/ 431 (0.9)	2.16 (0.67, 6.98)	0.1959	
	Moderate or severe secondary Immunodeficiency					NE
	Yes	0/ 23 (0.0)	0/ 20 (0.0)	NE		
	No	13/ 525 (2.5)	4/ 505 (0.8)	3.13 (1.03, 9.52)	0.0449	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
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NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	32 (5.8)	29 (5.5)
	Number of censored subjects, n (%)	516 (94.2)	496 (94.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.06 (0.65, 1.72)	
	p-value	0.8234	
	Odds Ratio (95% CI) [1]	1.06 (0.63, 1.78)	
	p-value	0.8234	
	Risk Difference (95% CI) [1]	0.32 (-2.45, 3.09)	
	p-value	0.8233	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
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Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	11 (2.0)	4 (0.8)
	Number of censored subjects, n (%)	537 (98.0)	521 (99.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.63 (0.84, 8.22)	
	p-value	0.0953	
	Odds Ratio (95% CI) [1]	2.67 (0.84, 8.43)	
	p-value	0.0946	
	Risk Difference (95% CI) [1]	1.25 (-0.14, 2.64)	
	p-value	0.0791	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	29 (5.3)	27 (5.1)
	Number of censored subjects, n (%)	519 (94.7)	498 (94.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.03 (0.62, 1.71)	
	p-value	0.9126	
	Odds Ratio (95% CI) [1]	1.03 (0.60, 1.77)	
	p-value	0.9126	
	Risk Difference (95% CI) [1]	0.15 (-2.51, 2.81)	
	p-value	0.9126	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 2: From first to second study intervention dose
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	12 (2.2)	4 (0.8)
	Number of censored subjects, n (%)	536 (97.8)	521 (99.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.87 (0.93, 8.85)	
	p-value	0.0659	
	Odds Ratio (95% CI) [1]	2.92 (0.93, 9.10)	
	p-value	0.0653	
	Risk Difference (95% CI) [1]	1.43 (-0.01, 2.86)	
	p-value	0.0509	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including one day prior to the second dosing date or Day 188 if no second dose was received.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	20 (3.6)	11 (2.1)
	Number of censored subjects, n (%)	528 (96.4)	514 (97.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.74 (0.84, 3.60)	
	p-value	0.1340	
	Odds Ratio (95% CI) [1]	1.77 (0.84, 3.73)	
	p-value	0.1334	
	Risk Difference (95% CI) [1]	1.55 (-0.44, 3.55)	
	p-value	0.1261	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Cardiac disorders	Number of subjects with events, n (%)	16 (2.9)	19 (3.6)
	Number of censored subjects, n (%)	532 (97.1)	506 (96.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.81 (0.42, 1.55)	
	p-value	0.5200	
	Odds Ratio (95% CI) [1]	0.80 (0.41, 1.57)	
	p-value	0.5199	
	Risk Difference (95% CI) [1]	-0.70 (-2.83, 1.43)	
	p-value	0.5200	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	8 (1.5)	13 (2.5)
	Number of censored subjects, n (%)	540 (98.5)	512 (97.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.59 (0.25, 1.41)	
	p-value	0.2353	
	Odds Ratio (95% CI) [1]	0.58 (0.24, 1.42)	
	p-value	0.2349	
	Risk Difference (95% CI) [1]	-1.02 (-2.68, 0.65)	
	p-value	0.2318	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Eye disorders	Number of subjects with events, n (%)	11 (2.0)	9 (1.7)
	Number of censored subjects, n (%)	537 (98.0)	516 (98.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.17 (0.49, 2.80)	
	p-value	0.7231	
	Odds Ratio (95% CI) [1]	1.17 (0.48, 2.86)	
	p-value	0.7230	
	Risk Difference (95% CI) [1]	0.29 (-1.32, 1.91)	
	p-value	0.7223	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	83 (15.1)	70 (13.3)
	Number of censored subjects, n (%)	465 (84.9)	455 (86.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.14 (0.85, 1.53)	
	p-value	0.3965	
	Odds Ratio (95% CI) [1]	1.16 (0.82, 1.64)	
	p-value	0.3962	
	Risk Difference (95% CI) [1]	1.81 (-2.37, 5.99)	
	p-value	0.3953	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	25 (4.6)	34 (6.5)
	Number of censored subjects, n (%)	523 (95.4)	491 (93.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.70 (0.43, 1.16)	
	p-value	0.1716	
	Odds Ratio (95% CI) [1]	0.69 (0.41, 1.17)	
	p-value	0.1712	
	Risk Difference (95% CI) [1]	-1.91 (-4.65, 0.82)	
	p-value	0.1703	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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NE: Not estimable

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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	17 (3.1)	17 (3.2)
	Number of censored subjects, n (%)	531 (96.9)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.49, 1.86)	
	p-value	0.8989	
	Odds Ratio (95% CI) [1]	0.96 (0.48, 1.89)	
	p-value	0.8989	
	Risk Difference (95% CI) [1]	-0.14 (-2.23, 1.96)	
	p-value	0.8989	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	109 (19.9)	115 (21.9)
	Number of censored subjects, n (%)	439 (80.1)	410 (78.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.91 (0.72, 1.15)	
	p-value	0.4173	
	Odds Ratio (95% CI) [1]	0.89 (0.66, 1.19)	
	p-value	0.4172	
	Risk Difference (95% CI) [1]	-2.01 (-6.88, 2.85)	
	p-value	0.4173	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Asthenia	Number of subjects with events, n (%)	17 (3.1)	17 (3.2)
	Number of censored subjects, n (%)	531 (96.9)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.49, 1.86)	
	p-value	0.8989	
	Odds Ratio (95% CI) [1]	0.96 (0.48, 1.89)	
	p-value	0.8989	
	Risk Difference (95% CI) [1]	-0.14 (-2.23, 1.96)	
	p-value	0.8989	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	29 (5.3)	44 (8.4)
	Number of censored subjects, n (%)	519 (94.7)	481 (91.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.63 (0.40, 0.99)	
	p-value	0.0468	
	Odds Ratio (95% CI) [1]	0.61 (0.38, 0.99)	
	p-value	0.0463	
	Risk Difference (95% CI) [1]	-3.09 (-6.11, -0.07)	
	p-value	0.0451	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Injection site bruising	Number of subjects with events, n (%)	7 (1.3)	10 (1.9)
	Number of censored subjects, n (%)	541 (98.7)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.67 (0.26, 1.75)	
	p-value	0.4139	
	Odds Ratio (95% CI) [1]	0.67 (0.25, 1.76)	
	p-value	0.4137	
	Risk Difference (95% CI) [1]	-0.63 (-2.13, 0.87)	
	p-value	0.4125	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Injection site pain	Number of subjects with events, n (%)	10 (1.8)	15 (2.9)
	Number of censored subjects, n (%)	538 (98.2)	510 (97.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.64 (0.29, 1.41)	
	p-value	0.2667	
	Odds Ratio (95% CI) [1]	0.63 (0.28, 1.42)	
	p-value	0.2664	
	Risk Difference (95% CI) [1]	-1.03 (-2.85, 0.78)	
	p-value	0.2644	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	21 (3.8)	18 (3.4)
	Number of censored subjects, n (%)	527 (96.2)	507 (96.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.12 (0.60, 2.07)	
	p-value	0.7242	
	Odds Ratio (95% CI) [1]	1.12 (0.59, 2.13)	
	p-value	0.7242	
	Risk Difference (95% CI) [1]	0.40 (-1.83, 2.64)	
	p-value	0.7237	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	231 (42.2)	212 (40.4)
	Number of censored subjects, n (%)	317 (57.8)	313 (59.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.04 (0.90, 1.20)	
	p-value	0.5558	
	Odds Ratio (95% CI) [1]	1.08 (0.84, 1.37)	
	p-value	0.5556	
	Risk Difference (95% CI) [1]	1.77 (-4.12, 7.66)	
	p-value	0.5554	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	13 (2.4)	7 (1.3)
	Number of censored subjects, n (%)	535 (97.6)	518 (98.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.78 (0.72, 4.42)	
	p-value	0.2151	
	Odds Ratio (95% CI) [1]	1.80 (0.71, 4.54)	
	p-value	0.2146	
	Risk Difference (95% CI) [1]	1.04 (-0.57, 2.65)	
	p-value	0.2054	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: COVID-19	Number of subjects with events, n (%)	60 (10.9)	83 (15.8)
	Number of censored subjects, n (%)	488 (89.1)	442 (84.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.69 (0.51, 0.94)	
	p-value	0.0201	
	Odds Ratio (95% CI) [1]	0.65 (0.46, 0.93)	
	p-value	0.0198	
	Risk Difference (95% CI) [1]	-4.86 (-8.93, -0.79)	
	p-value	0.0193	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Influenza	Number of subjects with events, n (%)	18 (3.3)	9 (1.7)
	Number of censored subjects, n (%)	530 (96.7)	516 (98.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (0.87, 4.23)	
	p-value	0.1072	
	Odds Ratio (95% CI) [1]	1.95 (0.87, 4.37)	
	p-value	0.1066	
	Risk Difference (95% CI) [1]	1.57 (-0.29, 3.43)	
	p-value	0.0980	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	21 (3.8)	14 (2.7)
	Number of censored subjects, n (%)	527 (96.2)	511 (97.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.44 (0.74, 2.80)	
	p-value	0.2856	
	Odds Ratio (95% CI) [1]	1.45 (0.73, 2.89)	
	p-value	0.2852	
	Risk Difference (95% CI) [1]	1.17 (-0.95, 3.28)	
	p-value	0.2806	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	16 (2.9)	10 (1.9)
	Number of censored subjects, n (%)	532 (97.1)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.53 (0.70, 3.35)	
	p-value	0.2837	
	Odds Ratio (95% CI) [1]	1.55 (0.70, 3.44)	
	p-value	0.2833	
	Risk Difference (95% CI) [1]	1.01 (-0.82, 2.85)	
	p-value	0.2774	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Rhinitis	Number of subjects with events, n (%)	10 (1.8)	10 (1.9)
	Number of censored subjects, n (%)	538 (98.2)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.40, 2.28)	
	p-value	0.9229	
	Odds Ratio (95% CI) [1]	0.96 (0.40, 2.32)	
	p-value	0.9229	
	Risk Difference (95% CI) [1]	-0.08 (-1.70, 1.54)	
	p-value	0.9229	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	10 (1.8)	6 (1.1)
	Number of censored subjects, n (%)	538 (98.2)	519 (98.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.60 (0.58, 4.36)	
	p-value	0.3615	
	Odds Ratio (95% CI) [1]	1.61 (0.58, 4.46)	
	p-value	0.3612	
	Risk Difference (95% CI) [1]	0.68 (-0.76, 2.13)	
	p-value	0.3543	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	36 (6.6)	24 (4.6)
	Number of censored subjects, n (%)	512 (93.4)	501 (95.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.44 (0.87, 2.38)	
	p-value	0.1572	
	Odds Ratio (95% CI) [1]	1.47 (0.86, 2.50)	
	p-value	0.1566	
	Risk Difference (95% CI) [1]	2.00 (-0.74, 4.74)	
	p-value	0.1526	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	29 (5.3)	28 (5.3)
	Number of censored subjects, n (%)	519 (94.7)	497 (94.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.99 (0.60, 1.64)	
	p-value	0.9759	
	Odds Ratio (95% CI) [1]	0.99 (0.58, 1.69)	
	p-value	0.9759	
	Risk Difference (95% CI) [1]	-0.04 (-2.73, 2.64)	
	p-value	0.9759	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	39 (7.1)	44 (8.4)
	Number of censored subjects, n (%)	509 (92.9)	481 (91.6)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.85 (0.56, 1.28)	
	p-value	0.4390	
	Odds Ratio (95% CI) [1]	0.84 (0.53, 1.31)	
	p-value	0.4389	
	Risk Difference (95% CI) [1]	-1.26 (-4.47, 1.94)	
	p-value	0.4390	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Investigations	Number of subjects with events, n (%)	18 (3.3)	13 (2.5)
	Number of censored subjects, n (%)	530 (96.7)	512 (97.5)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.33 (0.66, 2.68)	
	p-value	0.4310	
	Odds Ratio (95% CI) [1]	1.34 (0.65, 2.76)	
	p-value	0.4308	
	Risk Difference (95% CI) [1]	0.81 (-1.19, 2.81)	
	p-value	0.4278	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	34 (6.2)	28 (5.3)
	Number of censored subjects, n (%)	514 (93.8)	497 (94.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.16 (0.72, 1.89)	
	p-value	0.5415	
	Odds Ratio (95% CI) [1]	1.17 (0.70, 1.97)	
	p-value	0.5414	
	Risk Difference (95% CI) [1]	0.87 (-1.92, 3.66)	
	p-value	0.5403	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	59 (10.8)	59 (11.2)
	Number of censored subjects, n (%)	489 (89.2)	466 (88.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.68, 1.35)	
	p-value	0.8050	
	Odds Ratio (95% CI) [1]	0.95 (0.65, 1.40)	
	p-value	0.8050	
	Risk Difference (95% CI) [1]	-0.47 (-4.22, 3.27)	
	p-value	0.8051	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	10 (1.8)	10 (1.9)
	Number of censored subjects, n (%)	538 (98.2)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.40, 2.28)	
	p-value	0.9229	
	Odds Ratio (95% CI) [1]	0.96 (0.40, 2.32)	
	p-value	0.9229	
	Risk Difference (95% CI) [1]	-0.08 (-1.70, 1.54)	
	p-value	0.9229	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia	Number of subjects with events, n (%)	11 (2.0)	20 (3.8)
	Number of censored subjects, n (%)	537 (98.0)	505 (96.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.53 (0.25, 1.09)	
	p-value	0.0836	
	Odds Ratio (95% CI) [1]	0.52 (0.25, 1.09)	
	p-value	0.0831	
	Risk Difference (95% CI) [1]	-1.80 (-3.82, 0.21)	
	p-value	0.0796	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	21 (3.8)	11 (2.1)
	Number of censored subjects, n (%)	527 (96.2)	514 (97.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.83 (0.89, 3.76)	
	p-value	0.1001	
	Odds Ratio (95% CI) [1]	1.86 (0.89, 3.90)	
	p-value	0.0994	
	Risk Difference (95% CI) [1]	1.74 (-0.28, 3.76)	
	p-value	0.0921	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Nervous system disorders	Number of subjects with events, n (%)	68 (12.4)	68 (13.0)
	Number of censored subjects, n (%)	480 (87.6)	457 (87.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.70, 1.31)	
	p-value	0.7890	
	Odds Ratio (95% CI) [1]	0.95 (0.66, 1.36)	
	p-value	0.7890	
	Risk Difference (95% CI) [1]	-0.54 (-4.53, 3.44)	
	p-value	0.7891	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	40 (7.3)	41 (7.8)
	Number of censored subjects, n (%)	508 (92.7)	484 (92.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.93 (0.61, 1.42)	
	p-value	0.7518	
	Odds Ratio (95% CI) [1]	0.93 (0.59, 1.46)	
	p-value	0.7518	
	Risk Difference (95% CI) [1]	-0.51 (-3.67, 2.65)	
	p-value	0.7519	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	12 (2.2)	10 (1.9)
	Number of censored subjects, n (%)	536 (97.8)	515 (98.1)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.15 (0.50, 2.64)	
	p-value	0.7421	
	Odds Ratio (95% CI) [1]	1.15 (0.49, 2.69)	
	p-value	0.7421	
	Risk Difference (95% CI) [1]	0.29 (-1.41, 1.98)	
	p-value	0.7415	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	21 (3.8)	17 (3.2)
	Number of censored subjects, n (%)	527 (96.2)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.18 (0.63, 2.22)	
	p-value	0.5992	
	Odds Ratio (95% CI) [1]	1.19 (0.62, 2.28)	
	p-value	0.5991	
	Risk Difference (95% CI) [1]	0.59 (-1.61, 2.80)	
	p-value	0.5980	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	128 (23.4)	104 (19.8)
	Number of censored subjects, n (%)	420 (76.6)	421 (80.2)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.18 (0.94, 1.48)	
	p-value	0.1592	
	Odds Ratio (95% CI) [1]	1.23 (0.92, 1.65)	
	p-value	0.1585	
	Risk Difference (95% CI) [1]	3.55 (-1.37, 8.46)	
	p-value	0.1572	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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[1] Calculated using normal approximation (Wald).
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Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	55 (10.0)	53 (10.1)
	Number of censored subjects, n (%)	493 (90.0)	472 (89.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.99 (0.70, 1.42)	
	p-value	0.9745	
	Odds Ratio (95% CI) [1]	0.99 (0.67, 1.48)	
	p-value	0.9745	
	Risk Difference (95% CI) [1]	-0.06 (-3.66, 3.54)	
	p-value	0.9745	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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[1] Calculated using normal approximation (Wald).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Number of subjects with events, n (%)	13 (2.4)	5 (1.0)
	Number of censored subjects, n (%)	535 (97.6)	520 (99.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	2.49 (0.89, 6.94)	
	p-value	0.0808	
	Odds Ratio (95% CI) [1]	2.53 (0.89, 7.14)	
	p-value	0.0802	
	Risk Difference (95% CI) [1]	1.42 (-0.10, 2.94)	
	p-value	0.0673	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Number of subjects with events, n (%)	28 (5.1)	14 (2.7)
	Number of censored subjects, n (%)	520 (94.9)	511 (97.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (1.02, 3.60)	
	p-value	0.0432	
	Odds Ratio (95% CI) [1]	1.97 (1.02, 3.78)	
	p-value	0.0426	
	Risk Difference (95% CI) [1]	2.44 (0.14, 4.74)	
	p-value	0.0375	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Number of subjects with events, n (%)	36 (6.6)	19 (3.6)
	Number of censored subjects, n (%)	512 (93.4)	506 (96.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.82 (1.05, 3.12)	
	p-value	0.0313	
	Odds Ratio (95% CI) [1]	1.87 (1.06, 3.31)	
	p-value	0.0308	
	Risk Difference (95% CI) [1]	2.95 (0.33, 5.57)	
	p-value	0.0272	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Rhinorrhoea	Number of subjects with events, n (%)	33 (6.0)	33 (6.3)
	Number of censored subjects, n (%)	515 (94.0)	492 (93.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.96 (0.60, 1.53)	
	p-value	0.8573	
	Odds Ratio (95% CI) [1]	0.96 (0.58, 1.57)	
	p-value	0.8573	
	Risk Difference (95% CI) [1]	-0.26 (-3.14, 2.61)	
	p-value	0.8574	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	30 (5.5)	17 (3.2)
	Number of censored subjects, n (%)	518 (94.5)	508 (96.8)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.69 (0.94, 3.03)	
	p-value	0.0774	
	Odds Ratio (95% CI) [1]	1.73 (0.94, 3.18)	
	p-value	0.0768	
	Risk Difference (95% CI) [1]	2.24 (-0.20, 4.67)	
	p-value	0.0716	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Vascular disorders	Number of subjects with events, n (%)	27 (4.9)	24 (4.6)
	Number of censored subjects, n (%)	521 (95.1)	501 (95.4)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.08 (0.63, 1.84)	
	p-value	0.7844	
	Odds Ratio (95% CI) [1]	1.08 (0.62, 1.90)	
	p-value	0.7844	
	Risk Difference (95% CI) [1]	0.36 (-2.19, 2.90)	
	p-value	0.7842	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	9 (1.6)	14 (2.7)
	Number of censored subjects, n (%)	539 (98.4)	511 (97.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	0.62 (0.27, 1.41)	
	p-value	0.2517	
	Odds Ratio (95% CI) [1]	0.61 (0.26, 1.42)	
	p-value	0.2513	
	Risk Difference (95% CI) [1]	-1.02 (-2.77, 0.72)	
	p-value	0.2489	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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NE: Not estimable

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: General disorders and administration site conditions, PT: Fatigue	Age					0.1507
	< 65	22/ 360 (6.1)	27/ 352 (7.7)	0.80 (0.46, 1.37)	0.4124	
	>= 65	7/ 188 (3.7)	17/ 173 (9.8)	0.38 (0.16, 0.89)	0.0262	
	Sex					0.5533
	Male	16/ 249 (6.4)	30/ 274 (10.9)	0.59 (0.33, 1.05)	0.0727	
	Female	13/ 299 (4.3)	14/ 251 (5.6)	0.78 (0.37, 1.63)	0.5071	
	Region					0.3574
	US	15/ 323 (4.6)	13/ 272 (4.8)	0.97 (0.47, 2.01)	0.9380	
	Europe	10/ 158 (6.3)	19/ 173 (11.0)	0.58 (0.28, 1.20)	0.1415	
	Other	4/ 67 (6.0)	12/ 80 (15.0)	0.40 (0.13, 1.18)	0.0958	
	COVID-19 vaccination status within six months prior to randomization					0.7351
	Yes	4/ 74 (5.4)	8/ 78 (10.3)	0.53 (0.17, 1.68)	0.2780	
	No	25/ 474 (5.3)	36/ 447 (8.1)	0.65 (0.40, 1.07)	0.0928	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.8409
	Yes	2/ 24 (8.3)	3/ 27 (11.1)	0.75 (0.14, 4.12)	0.7405	
	No	27/ 524 (5.2)	41/ 498 (8.2)	0.63 (0.39, 1.00)	0.0507	
	AZD7442 use within 12 months prior to randomization					0.8427
	Yes	9/ 100 (9.0)	13/ 98 (13.3)	0.68 (0.30, 1.51)	0.3437	
	No	20/ 448 (4.5)	31/ 427 (7.3)	0.61 (0.36, 1.06)	0.0810	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.5704
	Yes	5/ 94 (5.3)	11/ 101 (10.9)	0.49 (0.18, 1.35)	0.1681	
	No	24/ 454 (5.3)	33/ 424 (7.8)	0.68 (0.41, 1.13)	0.1363	
	Solid organ or stem cell transplants					0.2974
	Yes	17/ 268 (6.3)	21/ 263 (8.0)	0.79 (0.43, 1.47)	0.4643	
	No	12/ 280 (4.3)	23/ 262 (8.8)	0.49 (0.25, 0.96)	0.0380	
	Solid tumor cancer and on active treatment					0.1433
	Yes	2/ 18 (11.1)	0/ 20 (0.0)	5.53 (0.28, 107.96)	0.2596	
	No	27/ 530 (5.1)	44/ 505 (8.7)	0.58 (0.37, 0.93)	0.0232	
	Taking immunosuppressive medicines					0.8365
	Yes	25/ 491 (5.1)	38/ 464 (8.2)	0.62 (0.38, 1.01)	0.0565	
	No	4/ 57 (7.0)	6/ 61 (9.8)	0.71 (0.21, 2.40)	0.5852	
	Electrocardiogram (ECG) interpretation					0.1103
	Normal	21/ 328 (6.4)	23/ 332 (6.9)	0.92 (0.52, 1.64)	0.7869	
	Abnormal	8/ 184 (4.3)	18/ 171 (10.5)	0.41 (0.18, 0.93)	0.0316	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
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SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: General disorders and administration site conditions, PT: Fatigue	Body Mass Index					0.5860
	<30 kg/m2	18/ 348 (5.2)	28/ 368 (7.6)	0.68 (0.38, 1.21)	0.1873	
	>=30 kg/m2	11/ 198 (5.6)	16/ 151 (10.6)	0.52 (0.25, 1.10)	0.0863	
	Hematological malignancies					0.6277
	Yes	6/ 100 (6.0)	11/ 94 (11.7)	0.51 (0.20, 1.33)	0.1700	
	No	23/ 448 (5.1)	33/ 431 (7.7)	0.67 (0.40, 1.12)	0.1287	
	Moderate or severe secondary Immunodeficiency					0.7479
	Yes	1/ 23 (4.3)	2/ 20 (10.0)	0.43 (0.04, 4.44)	0.4825	
	No	28/ 525 (5.3)	42/ 505 (8.3)	0.64 (0.40, 1.02)	0.0596	

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Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: COVID-19	Age					0.3771
	< 65	45/ 360 (12.5)	58/ 352 (16.5)	0.76 (0.53, 1.09)	0.1332	
	>= 65	15/ 188 (8.0)	25/ 173 (14.5)	0.55 (0.30, 1.01)	0.0547	
	Sex					0.1287
	Male	22/ 249 (8.8)	46/ 274 (16.8)	0.53 (0.33, 0.85)	0.0085	
	Female	38/ 299 (12.7)	37/ 251 (14.7)	0.86 (0.57, 1.31)	0.4893	
	Region					0.4360
	US	36/ 323 (11.1)	37/ 272 (13.6)	0.82 (0.53, 1.26)	0.3633	
	Europe	20/ 158 (12.7)	34/ 173 (19.7)	0.64 (0.39, 1.07)	0.0899	
	Other	4/ 67 (6.0)	12/ 80 (15.0)	0.40 (0.13, 1.18)	0.0958	
	COVID-19 vaccination status within six months prior to randomization					0.4524
	Yes	8/ 74 (10.8)	16/ 78 (20.5)	0.53 (0.24, 1.16)	0.1106	
	No	52/ 474 (11.0)	67/ 447 (15.0)	0.73 (0.52, 1.03)	0.0707	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.2781
	Yes	1/ 24 (4.2)	5/ 27 (18.5)	0.23 (0.03, 1.79)	0.1589	
	No	59/ 524 (11.3)	78/ 498 (15.7)	0.72 (0.52, 0.99)	0.0401	
	AZD7442 use within 12 months prior to randomization					0.8525
	Yes	12/ 100 (12.0)	16/ 98 (16.3)	0.74 (0.37, 1.47)	0.3850	
	No	48/ 448 (10.7)	67/ 427 (15.7)	0.68 (0.48, 0.97)	0.0307	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.1291
	Yes	8/ 94 (8.5)	21/ 101 (20.8)	0.41 (0.19, 0.88)	0.0220	
	No	52/ 454 (11.5)	62/ 424 (14.6)	0.78 (0.56, 1.10)	0.1640	
	Solid organ or stem cell transplants					0.2695
	Yes	32/ 268 (11.9)	38/ 263 (14.4)	0.83 (0.53, 1.28)	0.3939	
	No	28/ 280 (10.0)	45/ 262 (17.2)	0.58 (0.37, 0.90)	0.0161	
	Solid tumor cancer and on active treatment					0.1652
	Yes	2/ 18 (11.1)	0/ 20 (0.0)	5.53 (0.28, 107.96)	0.2596	
	No	58/ 530 (10.9)	83/ 505 (16.4)	0.67 (0.49, 0.91)	0.0107	
	Taking immunosuppressive medicines					0.2816
	Yes	58/ 491 (11.8)	76/ 464 (16.4)	0.72 (0.53, 0.99)	0.0435	
	No	2/ 57 (3.5)	7/ 61 (11.5)	0.31 (0.07, 1.41)	0.1289	
	Electrocardiogram (ECG) interpretation					0.8677
	Normal	42/ 328 (12.8)	60/ 332 (18.1)	0.71 (0.49, 1.02)	0.0633	
	Abnormal	17/ 184 (9.2)	21/ 171 (12.3)	0.75 (0.41, 1.38)	0.3563	

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SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Infections and infestations, PT: COVID-19	Body Mass Index					0.0499
	<30 kg/m2	33/ 348 (9.5)	63/ 368 (17.1)	0.55 (0.37, 0.82)	0.0034	
	>=30 kg/m2	26/ 198 (13.1)	18/ 151 (11.9)	1.10 (0.63, 1.93)	0.7360	
	Hematological malignancies					0.1833
	Yes	7/ 100 (7.0)	16/ 94 (17.0)	0.41 (0.18, 0.95)	0.0387	
	No	53/ 448 (11.8)	67/ 431 (15.5)	0.76 (0.54, 1.06)	0.1103	
	Moderate or severe secondary Immunodeficiency					0.8696
	Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.87 (0.06, 13.02)	0.9194	
	No	59/ 525 (11.2)	82/ 505 (16.2)	0.69 (0.51, 0.95)	0.0206	

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SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Age					0.5700
	< 65	20/ 360 (5.6)	9/ 352 (2.6)	2.17 (1.00, 4.71)	0.0491	
	>= 65	8/ 188 (4.3)	5/ 173 (2.9)	1.47 (0.49, 4.41)	0.4899	
	Sex					0.4877
	Male	13/ 249 (5.2)	9/ 274 (3.3)	1.59 (0.69, 3.65)	0.2752	
	Female	15/ 299 (5.0)	5/ 251 (2.0)	2.52 (0.93, 6.83)	0.0697	
	Region					0.6622
	US	16/ 323 (5.0)	9/ 272 (3.3)	1.50 (0.67, 3.33)	0.3232	
	Europe	8/ 158 (5.1)	3/ 173 (1.7)	2.92 (0.79, 10.81)	0.1087	
	Other	4/ 67 (6.0)	2/ 80 (2.5)	2.39 (0.45, 12.64)	0.3058	
	COVID-19 vaccination status within six months prior to randomization					0.4177
	Yes	3/ 74 (4.1)	3/ 78 (3.8)	1.05 (0.22, 5.06)	0.9475	
	No	25/ 474 (5.3)	11/ 447 (2.5)	2.14 (1.07, 4.30)	0.0321	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.3148
	Yes	3/ 24 (12.5)	0/ 27 (0.0)	7.84 (0.43, 144.45)	0.1660	
	No	25/ 524 (4.8)	14/ 498 (2.8)	1.70 (0.89, 3.23)	0.1067	
	AZD7442 use within 12 months prior to randomization					0.4403
	Yes	5/ 100 (5.0)	4/ 98 (4.1)	1.23 (0.34, 4.43)	0.7569	
	No	23/ 448 (5.1)	10/ 427 (2.3)	2.19 (1.06, 4.55)	0.0352	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.9140
	Yes	5/ 94 (5.3)	3/ 101 (3.0)	1.79 (0.44, 7.29)	0.4158	
	No	23/ 454 (5.1)	11/ 424 (2.6)	1.95 (0.96, 3.96)	0.0633	
	Solid organ or stem cell transplants					0.0699
	Yes	14/ 268 (5.2)	3/ 263 (1.1)	4.58 (1.33, 15.75)	0.0158	
	No	14/ 280 (5.0)	11/ 262 (4.2)	1.19 (0.55, 2.58)	0.6571	
	Solid tumor cancer and on active treatment					NE
	Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
	No	28/ 530 (5.3)	14/ 505 (2.8)	1.91 (1.02, 3.58)	0.0448	
	Taking immunosuppressive medicines					0.4365
	Yes	24/ 491 (4.9)	13/ 464 (2.8)	1.74 (0.90, 3.39)	0.0999	
	No	4/ 57 (7.0)	1/ 61 (1.6)	4.28 (0.49, 37.17)	0.1873	
	Electrocardiogram (ECG) interpretation					0.2624
	Normal	18/ 328 (5.5)	6/ 332 (1.8)	3.04 (1.22, 7.55)	0.0169	
	Abnormal	9/ 184 (4.9)	6/ 171 (3.5)	1.39 (0.51, 3.83)	0.5199	

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SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion	Body Mass Index					0.7934
	<30 kg/m2	17/ 348 (4.9)	9/ 368 (2.4)	2.00 (0.90, 4.42)	0.0879	
	>=30 kg/m2	11/ 198 (5.6)	5/ 151 (3.3)	1.68 (0.60, 4.73)	0.3274	
	Hematological malignancies					0.5350
	Yes	4/ 100 (4.0)	3/ 94 (3.2)	1.25 (0.29, 5.45)	0.7634	
	No	24/ 448 (5.4)	11/ 431 (2.6)	2.10 (1.04, 4.23)	0.0382	
	Moderate or severe secondary Immunodeficiency					0.5580
	Yes	1/ 23 (4.3)	1/ 20 (5.0)	0.87 (0.06, 13.02)	0.9194	
	No	27/ 525 (5.1)	13/ 505 (2.6)	2.00 (1.04, 3.83)	0.0370	

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SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Age					0.2672
	< 65	25/ 360 (6.9)	16/ 352 (4.5)	1.53 (0.83, 2.81)	0.1733	
	>= 65	11/ 188 (5.9)	3/ 173 (1.7)	3.37 (0.96, 11.89)	0.0585	
	Sex					0.4230
	Male	13/ 249 (5.2)	6/ 274 (2.2)	2.38 (0.92, 6.18)	0.0736	
	Female	23/ 299 (7.7)	13/ 251 (5.2)	1.49 (0.77, 2.87)	0.2395	
	Region					0.7520
	US	20/ 323 (6.2)	9/ 272 (3.3)	1.87 (0.87, 4.04)	0.1107	
	Europe	6/ 158 (3.8)	5/ 173 (2.9)	1.31 (0.41, 4.22)	0.6466	
	Other	10/ 67 (14.9)	5/ 80 (6.3)	2.39 (0.86, 6.64)	0.0955	
	COVID-19 vaccination status within six months prior to randomization					0.8151
	Yes	6/ 74 (8.1)	3/ 78 (3.8)	2.11 (0.55, 8.12)	0.2785	
	No	30/ 474 (6.3)	16/ 447 (3.6)	1.77 (0.98, 3.20)	0.0595	
	Prior SARS-CoV-2 infection within six months prior to randomization					0.6898
	Yes	1/ 24 (4.2)	0/ 27 (0.0)	3.36 (0.14, 78.79)	0.4515	
	No	35/ 524 (6.7)	19/ 498 (3.8)	1.75 (1.02, 3.02)	0.0440	
	AZD7442 use within 12 months prior to randomization					0.1733
	Yes	7/ 100 (7.0)	1/ 98 (1.0)	6.86 (0.86, 54.73)	0.0691	
	No	29/ 448 (6.5)	18/ 427 (4.2)	1.54 (0.87, 2.72)	0.1423	
	Prior COVID-19 vaccination or prior SARS-CoV-2 infection					0.7864
	Yes	6/ 94 (6.4)	3/ 101 (3.0)	2.15 (0.55, 8.35)	0.2693	
	No	30/ 454 (6.6)	16/ 424 (3.8)	1.75 (0.97, 3.17)	0.0637	
	Solid organ or stem cell transplants					0.2092
	Yes	16/ 268 (6.0)	12/ 263 (4.6)	1.31 (0.63, 2.71)	0.4697	
	No	20/ 280 (7.1)	7/ 262 (2.7)	2.67 (1.15, 6.22)	0.0224	
	Solid tumor cancer and on active treatment					NE
	Yes	0/ 18 (0.0)	0/ 20 (0.0)	NE		
	No	36/ 530 (6.8)	19/ 505 (3.8)	1.81 (1.05, 3.10)	0.0327	
	Taking immunosuppressive medicines					0.2870
	Yes	31/ 491 (6.3)	18/ 464 (3.9)	1.63 (0.92, 2.87)	0.0921	
	No	5/ 57 (8.8)	1/ 61 (1.6)	5.35 (0.64, 44.42)	0.1204	
	Electrocardiogram (ECG) interpretation					0.0550
	Normal	27/ 328 (8.2)	9/ 332 (2.7)	3.04 (1.45, 6.36)	0.0032	
	Abnormal	8/ 184 (4.3)	8/ 171 (4.7)	0.93 (0.36, 2.42)	0.8808	

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Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients) - Period 3: From first study intervention dose to end of study - Subgroup analysis
Safety Set 1 including only patients also part of full pre-exposure analysis set

SOC/PT	Subgroup Level	AZD3152/AZD3152 (N=548) n/ N (%)	Comparator (N=525) n/ N (%)	Analysis AZD3152/AZD3152 vs. Comparator Relative Risk (95% CI) [1]	p-Value	Interaction p-Value[2]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Body Mass Index					0.6806
	<30 kg/m2	22/ 348 (6.3)	14/ 368 (3.8)	1.66 (0.86, 3.20)	0.1279	
	>=30 kg/m2	14/ 198 (7.1)	5/ 151 (3.3)	2.14 (0.79, 5.80)	0.1366	
	Hematological malignancies					0.4095
	Yes	7/ 100 (7.0)	2/ 94 (2.1)	3.29 (0.70, 15.44)	0.1311	
	No	29/ 448 (6.5)	17/ 431 (3.9)	1.64 (0.92, 2.94)	0.0963	
	Moderate or severe secondary Immunodeficiency					0.8094
	Yes	1/ 23 (4.3)	0/ 20 (0.0)	2.63 (0.11, 61.05)	0.5477	
	No	35/ 525 (6.7)	19/ 505 (3.8)	1.77 (1.03, 3.06)	0.0397	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Subgroup analysis was done for SOCs / PTs with significant overall treatment effect (significant Relative Risk).
[1] Calculated using normal approximation (Wald).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	39 (7.1)	33 (6.3)
	Number of censored subjects, n (%)	509 (92.9)	492 (93.7)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.13 (0.72, 1.77)	
	p-value	0.5868	
	Odds Ratio (95% CI) [1]	1.14 (0.71, 1.85)	
	p-value	0.5867	
	Risk Difference (95% CI) [1]	0.83 (-2.16, 3.82)	
	p-value	0.5860	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	12 (2.2)	6 (1.1)
	Number of censored subjects, n (%)	536 (97.8)	519 (98.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (0.72, 5.07)	
	p-value	0.1901	
	Odds Ratio (95% CI) [1]	1.94 (0.72, 5.20)	
	p-value	0.1895	
	Risk Difference (95% CI) [1]	1.05 (-0.48, 2.57)	
	p-value	0.1787	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Infections and infestations	Number of subjects with events, n (%)	37 (6.8)	30 (5.7)
	Number of censored subjects, n (%)	511 (93.2)	495 (94.3)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.18 (0.74, 1.88)	
	p-value	0.4832	
	Odds Ratio (95% CI) [1]	1.19 (0.73, 1.96)	
	p-value	0.4831	
	Risk Difference (95% CI) [1]	1.04 (-1.85, 3.93)	
	p-value	0.4817	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	10 (1.8)	5 (1.0)
	Number of censored subjects, n (%)	538 (98.2)	520 (99.0)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (0.66, 5.57)	
	p-value	0.2322	
	Odds Ratio (95% CI) [1]	1.93 (0.66, 5.69)	
	p-value	0.2317	
	Risk Difference (95% CI) [1]	0.87 (-0.52, 2.27)	
	p-value	0.2203	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 SUPERNOVA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 29MAR2024
Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients) - Period 3: From first study intervention dose to end of study
Safety Set 1 including only patients also part of full pre-exposure analysis set

		AZD3152/AZD3152 (N=548)	Comparator (N=525)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	12 (2.2)	6 (1.1)
	Number of censored subjects, n (%)	536 (97.8)	519 (98.9)
	Unstratified Analysis AZD3152/AZD3152 vs. Comparator		
	Relative Risk (95% CI) [1]	1.92 (0.72, 5.07)	
	p-value	0.1901	
	Odds Ratio (95% CI) [1]	1.94 (0.72, 5.20)	
	p-value	0.1895	
	Risk Difference (95% CI) [1]	1.05 (-0.48, 2.57)	
	p-value	0.1787	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs that started, worsened, or became serious on or after the first investigational product dosing date up to and including the end of the study or data cutoff date.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

Anhang 4-G4: Ergebnisse zur Studie NOVELLA

Anhang 4-G4.1: Studienbeschreibung

Ergänzend dargestellte Studie NOVELLA

Analysepopulation

In der Studie NOVELLA wird für die Auswertungen das Full Analysis Set (FAS) herangezogen, welches alle Patient:innen umfasst, die mindestens eine Dosis der Studienmedikation erhalten haben. Für die Wirksamkeitsanalysen wird hierbei gemäß der in der Randomisierung zugewiesenen Behandlung analysiert. Für die Sicherheit erfolgte die Auswertung gemäß der tatsächlich verabreichten Studienmedikation. Alle Patienten des FAS der VO-Population erhielten die Studienmedikation, zu der sie randomisiert wurden, sodass für die Auswertungen zur Sicherheit das FAS auch dem Safety Analysis Set entspricht.

Analysezeitpunkte

In der Studie NOVELLA wurde der finale Analysezeitpunkt zur Visite an Tag 181 des letzten Patienten festgelegt. Zu Tag 91 war eine Visite vorgesehen und die präspezifizierten Endpunkte wurden erhoben.

Subgruppenmerkmale und andere Effektmodifikatoren

Für die Studie NOVELLA wurden für alle Endpunkte zunächst die Durchführbarkeit der Subgruppenanalysen geprüft, da aufgrund der geringen Anzahl an Studienteilnehmer:innen in der relevanten VO-Population die Voraussetzungen nicht für alle erhobenen Subgruppen erfüllt sind. Anschließend werden für alle Endpunkte und Subgruppen, die hinreichend geeignet sind zu den Merkmalen, die zu Studienbeginn erhoben wurden, die Subgruppenergebnisse dargestellt. Folgende Subgruppen werden hierbei geprüft und ggf. berichtet:

- Alter (<60 Jahre vs. ≥60 Jahre)
- Geschlecht (Männlich vs. Weiblich)
- BMI (<30 kg/m² vs. ≥30 kg/m²)
- EKG (Normal vs. Abnormal)
- Transplantation von soliden Organen oder Stammzellen (Ja vs. Nein)
- maligne solide Tumorerkrankungen oder hämatologische Malignität (Ja vs. Nein)
- Einnahme von immunsuppressiven Medikamenten (Ja vs. Nein)

Tabelle 4-G4.1-1: Charakterisierung der Studie NOVELLA

Studie	**Studiendesign** <RCT, doppelblind/einfach, verblindet/offen, parallel/cross-over etc.>	**Population** <relevante Charakteristika, z. B. Schweregrad>	**Interventionen (Zahl der randomisierten Patienten)**	**Studiendauer/ Datenschnitte** <ggf. Run-in, Behandlung, Nachbeobachtung>	**Ort und Zeitraum der Durchführung**	**Primärer Endpunkt; patientenrelevante sekundäre Endpunkte**
NOVELLA (ergänzend)	Multizentrische, randomisierte, doppelblinde, placebo-kontrollierte Phase-2-Studie; Zuteilungs-verhältnis: 3:1	Erwachsene ab 18 Jahren mit Erkrankungen, die zu einer Beeinträchtigung des Immunsystems führen	Randomisierte Patient:innen: Sipavibart (n=87) Placebo (n=29); Im Dossier dargestellte Analysepopulation: Sipavibart (n=15) Placebo (n=11)	Behandlungs- und Nachbeobach-tungsphase: sechs Monate Einschluss des ersten Patienten: 29. September 2023 Studiendauer: 29. September 2023 – 17. Mai 2024	8 Zentren in Russland	Primärer Endpunkt: UE SUE MAAE UESI Sekundäre Endpunkte: - Inzidenz eines symptomatischen COVID-19-Falls nach der Behandlung Explorative Endpunkte: - Anteil an Patient:innen mit Hospitalisierung aufgrund COVID-19
Alle verwendeten Abkürzungen werden im Abkürzungsverzeichnis erläutert.						

Tabelle 4-G4.1-2: Charakterisierung der Interventionen in der Studie NOVELLA

Studie	**Sipavibart**	**Kontrolle[a]**	***ggf. weitere Spalten mit Behandlungscharakteristika z. B. Vorbehandlung, Behandlung in der Run-in-Phase etc.***
NOVELLA (ergänzend)	Sipavibart (300 mg, angewendet als i.m. Injektion)	Placebo (i.m. Injektion) bestehend aus 0,9%iger Kochsalzlösung	SARS-CoV-2-Impfstoffe sollten nicht innerhalb der letzten sechs Monate vor der ersten Visite und nicht während der ersten 29 Tage der Studie verabreicht werden.

a: Für die Patient:innen war eine Dosiswiederholung der Studienmedikation nach 180 Tagen vorgesehen.
Alle verwendeten Abkürzungen werden im Abkürzungsverzeichnis erläutert.

Beschreibung der Studie NOVELLA

Die Studie NOVELLA ist eine abgeschlossene, russische, multizentrische, randomisierte, doppelblinde, kontrollierte Phase-2-Studie mit dem Ziel die Sicherheit von Sipavibart gegenüber Placebo zu bestimmen. Die Teilnehmer der Studie waren Erwachsene ab 18 Jahren mit Erkrankungen/Komorbiditäten, die zu einer Beeinträchtigung des Immunsystems führen, was ihr Risiko für eine unzureichende Reaktion auf eine aktive Immunisierung und für das Fortschreiten einer schweren COVID-19-Erkrankung erhöht. Die Patient:innen wurden im Verhältnis 3:1 zu Sipavibart oder Placebo randomisiert.

Die Behandlung erfolgte mit 300 mg Sipavibart bzw. einer 9 mg/mL-Kochsalzlösung, welche jeweils intramuskulär verabreicht wurden.

Die primären Endpunkte der Studie NOVELLA waren die Gesamtraten der UE, SUE, UE, die einer medizinischer Betreuung bedürfen (Medical Attended Adverse Events, MAAE) und UESI. Zudem wurden als sekundäre Endpunkte Antikörpertiter gegen bestimmte SARS-CoV-2-Varianten erhoben, sowie die Inzidenz der symptomatischen COVID-19 bestimmt.

Die Gesamtpopulation umfasst Patient:innen mit Erkrankungen/Komorbiditäten, welche das Risiko für einen schweren COVID-19-Verlauf erhöhen. Mögliche Risikofaktoren waren Übergewicht, Herzinsuffizienz, eine chronisch obstruktive Lungenerkrankung, chronische Nierenerkrankung, Intoleranz gegenüber SARS-CoV-2-Impfstoffen oder ein immungeschwächter Zustand. Insgesamt wurden 87 Patient:innen in den Sipavibart-Arm und 29 Patient:innen in den Kontroll-Arm randomisiert.

Analog zur Studie SUPERNOVA werden für die vorliegende Nutzenbewertung für die Studie NOVELLA – wie in Abschnitt 4.2.5.2 beschrieben – ebenfalls die Patient:innen berücksichtigt, die den in der COVID-19-Vorsorgeverordnung bzw. in der Empfehlung der STIKO zur Präexpositionsprophylaxe von COVID-19 (3) beschriebenen Kriterien entsprechen.

In diese bewertungsrelevante, eingeschränkte Population – mit VO-Population bezeichnet – werden Patient:innen eingeschlossen, die zu Studienbeginn mindestens eines der folgenden Kriterien erfüllen:

- nach autologer oder allogener Stammzelltransplantation vor immunologischer Rekonstitution
- unter oder nach Therapie mit Anti-B-Zell-Antikörpern, wenn keine Rekonstitution der B-Zell-Kapazitäten erfolgt ist
- unter CAR-T-Zell-Therapie
- unter starker Immunsuppression, z. B. nach Transplantation eines soliden Organs oder unter laufender Chemotherapie
- mit genetisch bedingten Immundefekten, die die antivirale Immunität beeinträchtigen

Die Kriterien wurden analog zum Vorgehen im Studienbericht, jeweils über Listen von zu Studienbeginn dokumentierten Vorerkrankungen oder verabreichten Arzneimitteln definiert (Tabelle 4-G4.1-3). Für Patient:innen mit malignen soliden Tumorerkrankungen und/oder hämatologischen Malignomen unter laufender Chemotherapie mussten zusätzlich zu Studienbeginn die Verabreichung einer der Wirkstoffe dokumentiert worden sein, deren Einnahme zur Behandlung einer malignen soliden Tumorerkrankung und/oder eines hämatologischen Malignoms die Berücksichtigung in der VO-Population begründet (Tabelle 4-17).

Tabelle 4-G4.1-3: Vorerkrankungen und Wirkstoffe, die einen Einschluss in die VO-Population der Studie NOVELLA begründen

Kriterium *Erfüllung des Kriteriums anhand von Vorerkrankungen bzw. verabreichter Wirkstoffe*
Maligne solide Tumorerkrankungen und/oder hämatologische Malignomen unter laufender Chemotherapie
Vorerkrankungen Akute myeloische Leukämie Basalzellkarzinom Brustkrebs Karzinom der Bronchien Zervixkarzinom Stadium III Chronische lymphatische Leukämie Kolonkarzinom Follikuläres Lymphom Morbus Hodgkin Lungenkarzinom nicht spezifizierten Zelltyps Stadium III Neubildung der Lunge bösartig Bösartiges Melanom Marginalzonenlymphom Myeloproliferative Neubildung Oesophaguskarzinom Neubildung der Ovarien Peritonealmesotheliom bösartig Plasmazellmyelom Prostatakarzinom Prostatakarzinom Stadium IV Kleinzelliges Lungenkarzinom Schilddruesenkrebs Stadium II Neubildung der Schilddrüse *Für den Einschluss in die VO-Population musste zusätzlich die Verabreichung einer der Wirkstoffe aus 4-17 zu Studienbeginn dokumentiert worden sein.*
Transplantation eines soliden Organs
Vorerkrankungen Lebertransplantation Nierentransplantation Herztransplantation
CAR-T-Zell-Therapie
Wirkstoffe Tisagenlecleucel Axicabtagen ciloleucel Brexucabtagen autoleucel Lisocabtagen maraleucel Idecabtagen vicleucel Ciltacabtagen autoleucel

Kriterium *Erfüllung des Kriteriums anhand von Vorerkrankungen bzw. verabreichter Wirkstoffe*
Therapie mit Anti-B-Zell-Antikörpern
Wirkstoffe Rituximab Ofatumumab Obinutuzumab Ocrelizumab Mosunetuzumab
Genetisch bedingte Immundefekte, die die antivirale Immunität beeinträchtigen
In der Studie NOVELLA wurden keine Patient:innen mit relevanten genetisch bedingten Immundefekten identifiziert
Die vorliegende Liste ergibt sich aus der Prüfung der Studiendokumente, der verabreichten Wirkstoffe und Vorerkrankungen in der Studie NOVELLA sowie dem Review durch medizinische Experten.

Nach Anwendung der beschriebenen Kriterien auf die Studienpopulation umfasst das FAS der VO-Population insgesamt 26 Patient:innen. Davon wurden 15 Patient:innen in den Sipavibart-Arm und 11 Patient:innen in den Kontroll-Arm randomisiert.

Verzerrungspotenzial auf Studienebene

Tabelle 4-G4.1-4: Verzerrungspotenzial auf Studienebene der Studie NOVELLA

Studie	**Adäquate Erzeugung der Randomisierungs-sequenz**	**Verdeckung der Gruppenzuteilung**	**Verblindung**		**Ergebnisunabhängige Berichterstattung**	**Keine sonstigen Aspekte**	**Verzerrungspotenzial auf Studienebene**
			Patient	**Behandelnde Personen**			
NOVELLA (ergänzend)	Ja	Ja	Ja	Ja	Ja	Ja	Niedrig
Alle verwendeten Abkürzungen werden im Abkürzungsverzeichnis erläutert.							

Die ergänzend dargestellte Studie NOVELLA ist eine doppelblinde, randomisierte Studie. Die Randomisierung wurde mittels IRT adäquat durchgeführt. Vor Beginn der Studie wurden jedem Studienzentrum Anleitungen, Anmeldeinformationen und Anweisungen für das IRT zur Verfügung gestellt. Die Gruppenzugehörigkeit erfolgte in der Studie NOVELLA zentral und unabhängig im Zuteilungsverhältnis 3:1. Sowohl die Patient:innen als auch die behandelnden Prüfärzt:innen waren verblindet.

Das Ziel der Studie NOVELLA war primär die Untersuchung der Sicherheit und sekundär die Messung der Titer für neutralisierende Antikörper gegen die neuen dominanten SARS-CoV-2-Varianten. Eine formale statistische Hypothese lag nicht vor und der Bericht erfolgte nach deskriptiver und explorativer Natur. Für diese Fragestellung ist die Betrachtung einer kleineren Studienpopulation hinreichend. Für die Fragestellung der vorliegenden Nutzenbewertung, bei der insbesondere die Wirksamkeit und Sicherheit von Sipavibart beurteilt werden soll, ist die Anzahl der Patienten sehr gering.

Unter Berücksichtigung der aufgeführten Aspekte wird das Verzerrungspotenzial der Studie NOVELLA auf Studienebene abschließend als niedrig eingestuft. Die Studie wird für die Zusatznutzenbewertung nicht herangezogen. Sie wird im Folgenden nur ergänzend dargestellt und auf eine Bewertung des Verzerrungspotenzials auf Endpunktebene wird verzichtet.

Tabelle 4-G4.1-5: Matrix der Endpunkte der Studie NOVELLA

Studie	Mortalität	Symptomspezifische Wirksamkeit	Gesundheitsbezogene Lebensqualität	Sicherheit
NOVELLA (ergänzend)	Ja	Ja	Nein	Ja
Alle verwendeten Abkürzungen werden im Abkürzungsverzeichnis erläutert.				

Ergebnisse der Studie NOVELLA

Tabelle 4-G4.1-6: Operationalisierung der Endpunkte in der Studie NOVELLA

Endpunkt	Operationalisierung
Gesamtmortalität	Gesamtmortalität und Tod aufgrund von COVID-19 sind analog zur Studie SUPERNOVA operationalisiert.
Symptomspezifische Wirksamkeit	Anteil an Patient:innen mit einer symptomatischen COVID-19-Erkrankung Eine symptomatische COVID-19 ist definiert als: - Vorliegen eines positiven RT-PCR-Tests oder Antigentests zu einem beliebigen Zeitpunkt bis Monat 6 unter Patient:innen, die zu Studienbeginn einen negativen RT-PCR-Test aufwiesen und - Erfüllung der modifizierten WHO-Definition einer symptomatischen COVID-19 Um die Inzidenz der COVID-19 zu ermitteln, werden die Patient:innen wöchentlich von den Zentren kontaktiert. Patient:innen, die entblindet werden und/oder ein weiteres Präparat zur Prävention der COVID-19 erhalten, werden als Patient:innen ohne COVID-19-Ereignis gewertet. Kombinierter Endpunkt aus Hospitalisierung aufgrund COVID-19 oder Tod aufgrund COVID-19 Der Endpunkt wird erreicht, wenn Tod aufgrund COVID-19 eintritt oder der Patient/die Patientin aufgrund von COVID-19 hospitalisiert werden muss. Dabei reichte es nicht aus, wenn der Patient/die Patientin ausschließlich hospitalisiert wurde, um isoliert zu werden. Zusätzlich zu dem kombinierten Endpunkt werden die Einzelkomponenten Tod aufgrund COVID-19 und Hospitalisierung aufgrund COVID-19 auch separat berichtet[a]. Patient:innen, die entblindet werden und/oder ein weiteres Präparat zur Prävention der COVID-19 erhalten, werden als Patient:innen ohne COVID-19-Ereignis gewertet. Der Endpunkt wird mit einer binären Analyse zu den Anteilen der Patient:innen mit Hospitalisierung aufgrund COVID-19 oder Tod aufgrund COVID-19 untersucht.
Sicherheit	Alle Endpunkte zur Sicherheit sind analog zur Studie SUPERNOVA operationalisiert.
Alle verwendeten Abkürzungen werden im Abkürzungsverzeichnis erläutert.	

Subgruppenanalysen

In der Studie NOVELLA ergibt sich aufgrund der geringen Patientenzahlen und der sehr wenigen Ereignisse bei den betrachteten Endpunkten keine aussagekräftige Evidenz zwischen den Behandlungsgruppen. In der Population, welche der COVID-19-Vorsorgeverordnung und den Kriterien der STIKO entspricht, die Patient:innen mit Erkrankungen, die zu einer Beeinträchtigung des Immunsystems führen, umfasst, wurden lediglich 26 Patienten betrachtet, davon waren 15 Patient:innen in den Sipavibart-Arm und 11 Patient:innen in den Komparator-Arm randomisiert.

Zusammenfassung Beurteilung der Aussagekraft der Nachweise

Die Studie NOVELLA ist eine abgeschlossene, russische, multizentrische, randomisierte, doppelblinde, kontrollierte Phase-2-Studie an 8 Zentren mit insgesamt 116 randomisierten Patient:innen und einer Beobachtungsdauer von bis zu 6 Monaten. Die Teilnehmer:innen der Studie waren Erwachsene ab 18 Jahren mit mindestens 45 kg Körpergewicht, bei denen aufgrund von Erkrankungen, Vorerkrankungen und/oder Therapien eine Beeinträchtigung des Immunsystems vorlag. Die Patient:innen wurden in der Studie NOVELLA im Verhältnis 3:1 randomisiert. Die Studie NOVELLA wird ergänzend dargestellt.

Anhang 4-G4.2: Ergebnisse

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Disposition
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)	Total (N=26)
Randomized Subjects	15 (100.0)	11 (100.0)	26 (100.0)
Subjects who were randomized but not dosed	0 (0.0)	0 (0.0)	0 (0.0)
Subjects who received study intervention	15 (100.0)	11 (100.0)	26 (100.0)
Randomized subjects who completed the study	14 (93.3)	10 (90.9)	24 (92.3)
Subjects discontinued from study	1 (6.7)	1 (9.1)	2 (7.7)
Physician Decision	1 (6.7)	0 (0.0)	1 (3.8)
Withdrawal By Subject	0 (0.0)	1 (9.1)	1 (3.8)
Full analysis set	15 (100.0)	11 (100.0)	26 (100.0)
Safety analysis set	15 (100.0)	11 (100.0)	26 (100.0)
SARS-CoV-2 neutralizing antibody (nAb) analysis set	15 (100.0)	11 (100.0)	26 (100.0)

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Inclusion Criteria
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)	Total (N=26)
Inclusion based on one criterion only				
	Any Criteria	15 (100.0)	11 (100.0)	26 (100.0)
	Active solid tumors and hematologic malignancies under chemotherapy	4 (26.7)	6 (54.5)	10 (38.5)
	Solid organ transplant and hematopoetic stem cell transplant	8 (53.3)	3 (27.3)	11 (42.3)
	Received chimeric antigen receptor T-Cell therapy	0 (0.0)	0 (0.0)	0 (0.0)
	Within one year of receiving B-Cell depleting Therapies	3 (20.0)	2 (18.2)	5 (19.2)
Inclusion based on multiple criteria				
	>=2 inclusion criteria fullfilled	0 (0.0)	0 (0.0)	0 (0.0)
Inclusion based on single criterion [1]				
	Active solid tumors and hematologic malignancies under chemotherapy	4 (26.7)	6 (54.5)	10 (38.5)
	Solid organ transplant and hematopoetic stem cell transplant	8 (53.3)	3 (27.3)	11 (42.3)
	Received chimeric antigen receptor T-Cell therapy	0 (0.0)	0 (0.0)	0 (0.0)
	Within one year of receiving B-Cell depleting Therapies	3 (20.0)	2 (18.2)	5 (19.2)

[1] Patients can be in multiple criteria, hence percentages do not sum up to 100.

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STIKO Covid-19 pre-exposition recommendation Population
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Immunocompromised conditions with comorbidities/disease characteristics on baseline
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)	Total (N=26)
Any condition	15 (100.0)	11 (100.0)	26 (100.0)
Obesity	5 (33.3)	2 (18.2)	7 (26.9)
Active solid tumors and hematologic malignancies	4 (26.7)	6 (54.5)	10 (38.5)
Chronic Lymphocytic Leukaemia	2 (13.3)	3 (27.3)	5 (19.2)
Lung Neoplasm Malig T	0 (0.0)	2 (18.2)	2 (7.7)
Acute Myeloid Leukaemia	0 (0.0)	1 (9.1)	1 (3.8)
Lung Carcinoma Cell Type Unspecified Stage Iii	1 (6.7)	0 (0.0)	1 (3.8)
Prostate Cancer	1 (6.7)	0 (0.0)	1 (3.8)
Small Cell Lung Cancer	1 (6.7)	0 (0.0)	1 (3.8)
Actively taking immunosuppressive medicines	3 (20.0)	2 (18.2)	5 (19.2)
Rheumatoid Arthritis	2 (13.3)	1 (9.1)	3 (11.5)
Ankylosing Spondylitis	1 (6.7)	0 (0.0)	1 (3.8)
Systemic Lupus Erythematosus	0 (0.0)	1 (9.1)	1 (3.8)
Chronic obstructive pulmonary disease	4 (26.7)	1 (9.1)	5 (19.2)
Chronic Obstructive Pulmonary Disease	4 (26.7)	1 (9.1)	5 (19.2)
Solid organ transplant or a hematopoietic stem cell transplant	8 (53.3)	3 (27.3)	11 (42.3)
Heart Transplant	6 (40.0)	1 (9.1)	7 (26.9)
Renal Transplant	2 (13.3)	1 (9.1)	3 (11.5)
Liver Transplant	0 (0.0)	1 (9.1)	1 (3.8)
Congestive heart failure	0 (0.0)	1 (9.1)	1 (3.8)
Cardiac Failure Chronic	0 (0.0)	1 (9.1)	1 (3.8)
Chronic kidney disease	4 (26.7)	0 (0.0)	4 (15.4)
Chronic Kidney Disease	4 (26.7)	0 (0.0)	4 (15.4)

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Demographic and Disease Characteristics
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)	Total (N=26)
Age (years)	n (missing)	15 (0)	11 (0)	26 (0)
	Mean (SD)	60.20 (9.329)	54.55 (11.457)	57.81 (10.458)
	Median	61.00	57.00	58.00
	Q1, Q3	55.00, 67.00	44.00, 65.00	54.00, 65.00
	Min, Max	38.0, 78.0	35.0, 69.0	35.0, 78.0
Age Group (years), n (%)	>= 18 to < 60	7 (46.7)	7 (63.6)	14 (53.8)
	>= 60	8 (53.3)	4 (36.4)	12 (46.2)
Sex, n (%)	Male	13 (86.7)	6 (54.5)	19 (73.1)
	Female	2 (13.3)	5 (45.5)	7 (26.9)
Race, n (%)	White	15 (100.0)	11 (100.0)	26 (100.0)
Ethnicity, n (%)	Not Hispanic or Latino	15 (100.0)	10 (90.9)	25 (96.2)
	Missing	0	1 (9.1)	1 (3.8)
Height (cm)	n (missing)	15 (0)	11 (0)	26 (0)
	Mean (SD)	174.27 (7.564)	172.64 (10.652)	173.58 (8.837)
	Median	175.00	172.00	175.00
	Q1, Q3	171.00, 178.00	162.00, 180.00	166.00, 180.00
	Min, Max	158.0, 189.0	158.0, 188.0	158.0, 189.0
Weight (kg)	n (missing)	15 (0)	11 (0)	26 (0)
	Mean (SD)	84.75 (15.371)	78.69 (21.121)	82.19 (17.891)
	Median	79.00	86.00	79.85
	Q1, Q3	74.30, 96.30	59.00, 97.00	68.00, 96.30
	Min, Max	65.0, 118.0	52.2, 113.0	52.2, 118.0
BMI (kg/m^2)	n (missing)	15 (0)	11 (0)	26 (0)
	Mean (SD)	27.87 (4.719)	25.82 (4.687)	27.00 (4.724)
	Median	27.00	25.00	26.50
	Q1, Q3	25.00, 30.00	20.00, 30.00	24.00, 30.00
	Min, Max	21.0, 38.0	20.0, 33.0	20.0, 38.0
Previous COVID-19 vaccinations, n (%)		9 (60.0)	5 (45.5)	14 (53.8)
Brand of last COVID-19 vaccine, n (%)	Sputnik V/Sputnik Light	9 (100.0)	4 (80.0)	13 (92.9)
	Unknown	0	1 (20.0)	1 (7.1)
Number of prior COVID-19 vaccinations received	n (missing)	9 (6)	5 (6)	14 (12)
	Mean (SD)	1.78 (0.667)	1.20 (0.447)	1.57 (0.646)
	Median	2.00	1.00	1.50
	Q1, Q3	1.00, 2.00	1.00, 1.00	1.00, 2.00
	Min, Max	1.0, 3.0	1.0, 2.0	1.0, 3.0
Whether any bivalent booster was received or not, n (%)	No	8 (88.9)	4 (80.0)	12 (85.7)
Time (months) from last COVID-19 infection reported	n (missing)	9 (6)	8 (3)	17 (9)
	Mean (SD)	24.33 (10.559)	28.13 (10.021)	26.12 (10.173)
	Median	21.00	27.00	21.00
	Q1, Q3	20.00, 29.00	20.50, 37.50	20.00, 34.00
	Min, Max	7.0, 42.0	14.0, 41.0	7.0, 42.0

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Demographic and Disease Characteristics
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)	Total (N=26)
Number of prior confirmed COVID-19 Infections	n (missing)	9 (6)	8 (3)	17 (9)
	Mean (SD)	1.22 (0.441)	1.00 (0.000)	1.12 (0.332)
	Median	1.00	1.00	1.00
	Q1, Q3	1.00, 1.00	1.00, 1.00	1.00, 1.00
	Min, Max	1.0, 2.0	1.0, 1.0	1.0, 2.0
Whether the previous COVID-19 infection led to hospitalization in the past 6 month, n (%)	No	9 (60.0)	8 (72.7)	17 (65.4)

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Datacut: 11JUL2024
Follow-up durations Study/Treatment
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)
Study duration (Days) [1]	n (missing)	15 (0)	11 (0)
	Mean (SD)	179.40 (9.963)	181.00 (9.990)
	Median	176.00	181.00
	Q1, Q3	171.00, 188.00	169.00, 192.00
	Min, Max	167.0, 197.0	167.0, 195.0

[1] From treatment start date to min(Data cutoff, study discontinuation, last follow-up, death, study completion date).

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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Follow-up durations Safety
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
Safety Follow-up duration (Days) [1]	n (missing)	15 (0)	11 (0)
	Mean (SD)	173.13 (23.934)	178.64 (15.299)
	Median	174.00	181.00
	Q1, Q3	171.00, 184.00	169.00, 192.00
	Min, Max	94.0, 197.0	141.0, 195.0
Duration of Follow-up period (Days) [2]	n (missing)	15 (0)	11 (0)
	Mean (SD)	179.40 (9.963)	181.00 (9.990)
	Median	176.00	181.00
	Q1, Q3	171.00, 188.00	169.00, 192.00
	Min, Max	167.0, 197.0	167.0, 195.0

[1] From treatment start date to min(Data cutoff, last safety assessment).
[2] From treatment start date to date of last contact.

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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Follow-up durations Overall Mortality
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)
Overall Mortality (CUTOFF DAY 90) Follow-up duration (Days) [1]	n (missing)	15 (0)	11 (0)
	Mean (SD)	91.00 (0.000)	91.00 (0.000)
	Median	91.00	91.00
	Q1, Q3	91.00, 91.00	91.00, 91.00
	Min, Max	91.0, 91.0	91.0, 91.0
Overall Mortality - COVID-19 related (CUTOFF DAY 90) Follow-up duration (Days) [2]	n (missing)	15 (0)	11 (0)
	Mean (SD)	91.00 (0.000)	91.00 (0.000)
	Median	91.00	91.00
	Q1, Q3	91.00, 91.00	91.00, 91.00
	Min, Max	91.0, 91.0	91.0, 91.0
Overall Mortality Follow-up duration (Days) [3]	n (missing)	15 (0)	11 (0)
	Mean (SD)	179.40 (9.963)	181.00 (9.990)
	Median	176.00	181.00
	Q1, Q3	171.00, 188.00	169.00, 192.00
	Min, Max	167.0, 197.0	167.0, 195.0
Overall Mortality - COVID-19 related Follow-up duration (Days) [4]	n (missing)	15 (0)	11 (0)
	Mean (SD)	179.40 (9.963)	181.00 (9.990)
	Median	176.00	181.00
	Q1, Q3	171.00, 188.00	169.00, 192.00
	Min, Max	167.0, 197.0	167.0, 195.0

[1] From first dose up to min(Day 90, early withdrawal, lost to follow-up, data cutoff, death)
[2] From first dose up to min(Day 90, early withdrawal, lost to follow-up, data cutoff, COVID-related death)
[3] From first dose up to min(Early withdrawal, lost to follow-up, data cutoff, death)
[4] From first dose up to min(Early withdrawal, lost to follow-up, data cutoff, COVID-related death)

AstraZeneca: Final
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Datacut: 11JUL2024
Follow-up durations COVID (CUTOFF DAY 90)
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)
Symptomatic COVID-19 (CUTOFF DAY 90) Follow-up duration (Days) [1]	n (missing)	15 (0)	11 (0)
	Mean (SD)	91.00 (0.000)	87.18 (12.663)
	Median	91.00	91.00
	Q1, Q3	91.00, 91.00	91.00, 91.00
	Min, Max	91.0, 91.0	49.0, 91.0
COVID-19 related hospitalization or death (CUTOFF DAY 90) Follow-up duration (Days) [2]	n (missing)	15 (0)	11 (0)
	Mean (SD)	91.00 (0.000)	91.00 (0.000)
	Median	91.00	91.00
	Q1, Q3	91.00, 91.00	91.00, 91.00
	Min, Max	91.0, 91.0	91.0, 91.0

[1] From first dose up to min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, Day 90, early withdrawal, lost to follow-up, data cutoff, COVID related AE).
[2] From first dose up to min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, Day 90, early withdrawal, lost to follow-up, data cutoff, COVID-related death, COVID-related hospitalization).
COVID-19 preventive products: Nirmatrelvir+Ritonavir, Molnupiravir, Remdesivir, Pemivibart, Nirmatrelvir, Ritonavir

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Follow-up durations COVID
Full analysis Set

		AZD3152 (N=15)	Placebo (N=11)
Symptomatic COVID-19 Follow-up duration (Days) [1]	n (missing)	15 (0)	11 (0)
	Mean (SD)	179.40 (9.963)	169.00 (41.034)
	Median	176.00	181.00
	Q1, Q3	171.00, 188.00	168.00, 192.00
	Min, Max	167.0, 197.0	49.0, 195.0
COVID-19 related hospitalization or death Follow-up duration (Days) [2]	n (missing)	15 (0)	11 (0)
	Mean (SD)	179.40 (9.963)	181.00 (9.990)
	Median	176.00	181.00
	Q1, Q3	171.00, 188.00	169.00, 192.00
	Min, Max	167.0, 197.0	167.0, 195.0

[1] From first dose up to min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, early withdrawal, lost to follow-up, data cutoff, COVID related AE).
[2] From first dose up to min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, early withdrawal, lost to follow-up, data cutoff, COVID-related death, COVID-related hospitalization).
COVID-19 preventive products: Nirmatrelvir+Ritonavir, Molnupiravir, Remdesivir, Pemivibart, Nirmatrelvir, Ritonavir

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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Day 90, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	AZD3152 (N=15) Median (95% CI)[1]	Placebo (N=11) n/ N (%)	Placebo (N=11) Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	Unstratified analysis p-Value[3]	Interaction p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		0/ 4 (0.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		0/ 5 (0.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		0/ 8 (0.0)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		0/ 8 (0.0)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		0/ 6 (0.0)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		0/ 9 (0.0)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
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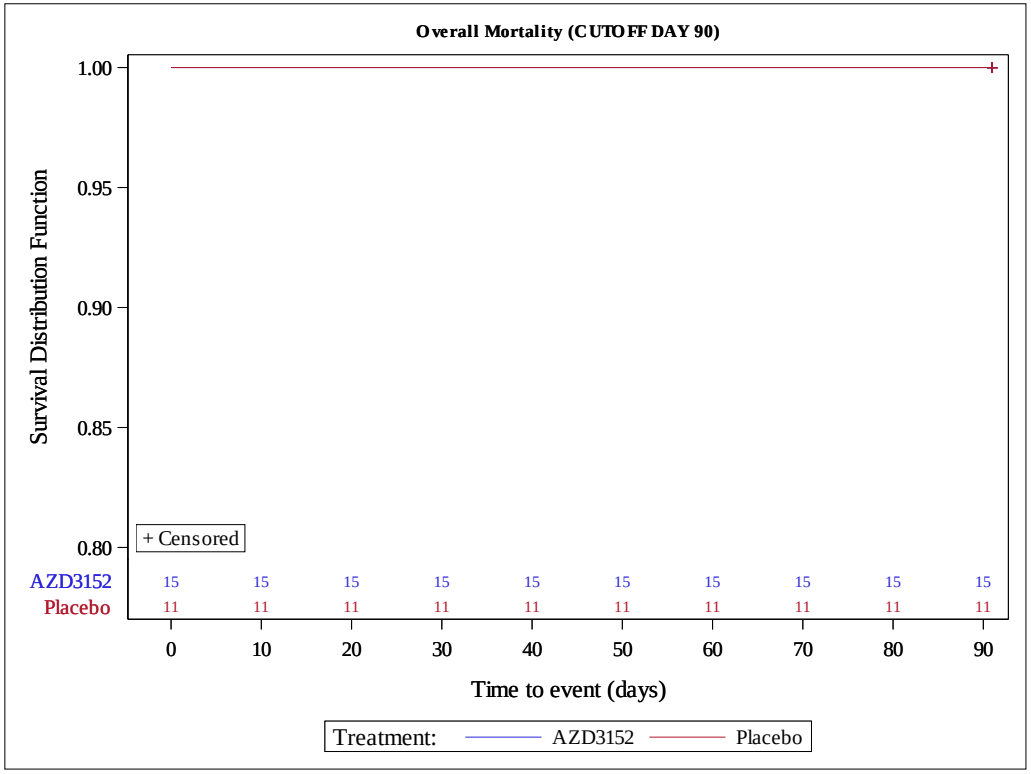
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Overall Mortality (CUTOFF DAY 90)
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
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STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality - Subgroup analysis
Full analysis Set

Subgroup	AZD3152 (N=15)		Placebo (N=11)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		0/ 4 (0.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		0/ 5 (0.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		0/ 8 (0.0)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		0/ 8 (0.0)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		0/ 6 (0.0)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		0/ 9 (0.0)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
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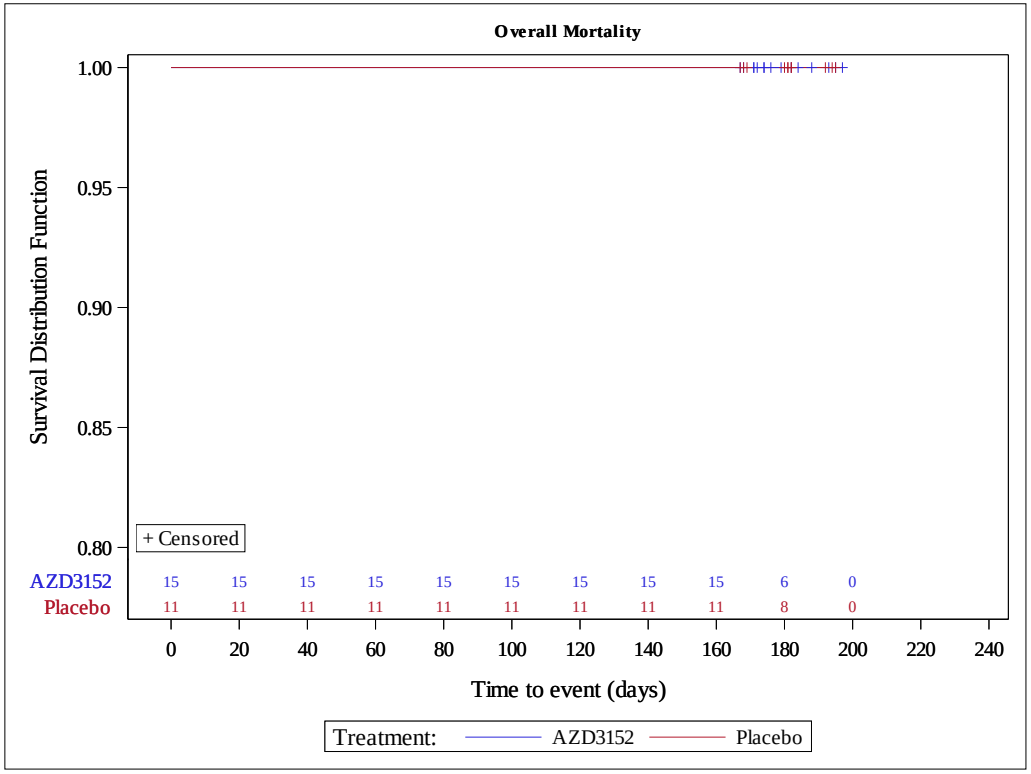
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Overall Mortality
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Day 90, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
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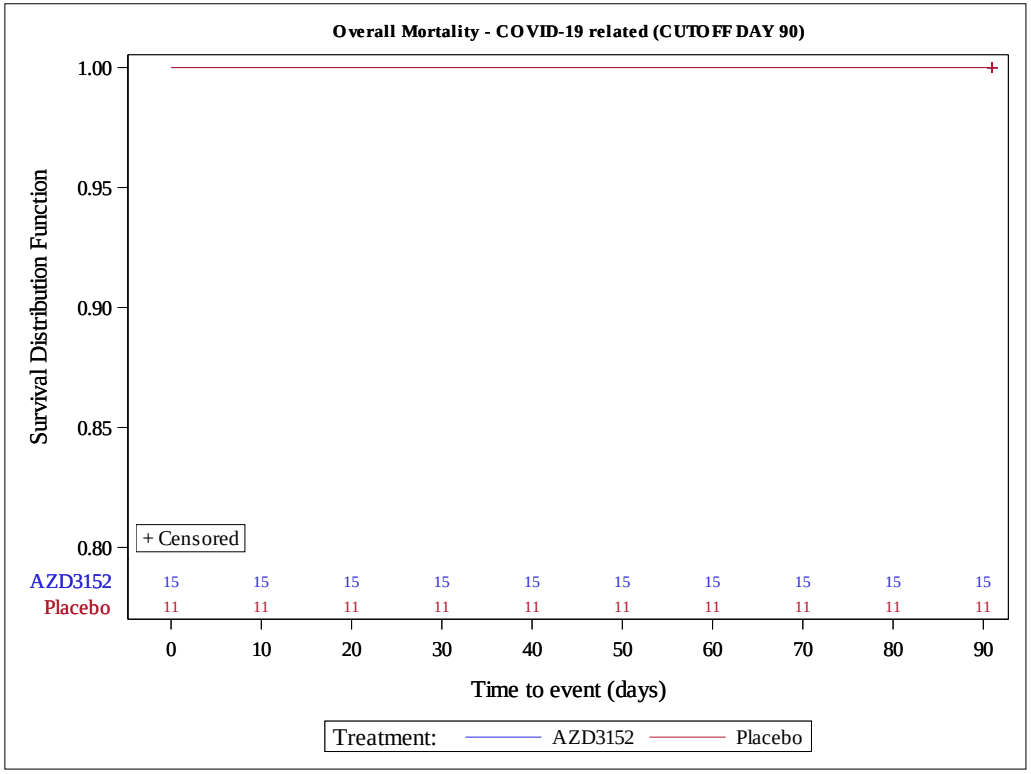
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality - COVID-19 related (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	AZD3152 (N=15) Median (95% CI)[1]	Placebo (N=11) n/ N (%)	Placebo (N=11) Median (95% CI)[1]	Unstratified analysis Hazard Ratio (95% CI)[2]	Unstratified analysis p-Value[3]	Interaction p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		0/ 4 (0.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		0/ 5 (0.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		0/ 8 (0.0)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		0/ 8 (0.0)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		0/ 6 (0.0)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		0/ 9 (0.0)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Overall Mortality - COVID-19 related (CUTOFF DAY 90)
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality - COVID-19 related
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

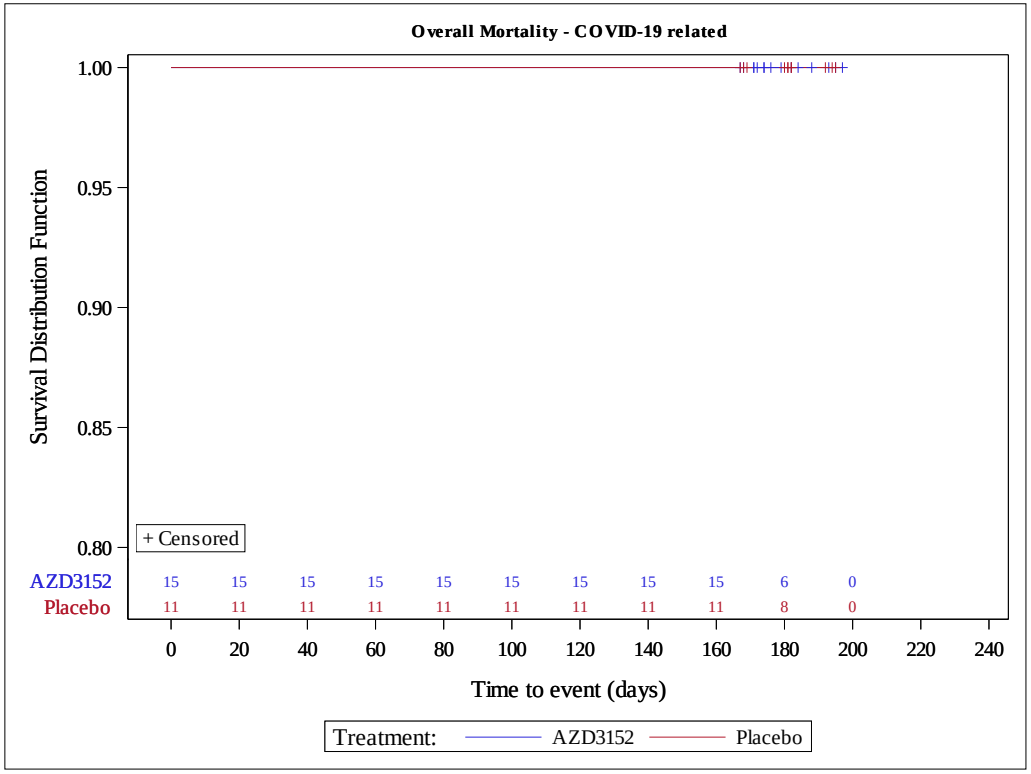
Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Overall Mortality - COVID-19 related - Subgroup analysis
Full analysis Set

Subgroup	AZD3152 (N=15)		Placebo (N=11)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		0/ 4 (0.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		0/ 5 (0.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		0/ 8 (0.0)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		0/ 8 (0.0)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		0/ 6 (0.0)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		0/ 9 (0.0)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Overall Mortality - COVID-19 related
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of symptomatic COVID-19 (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (49.0, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

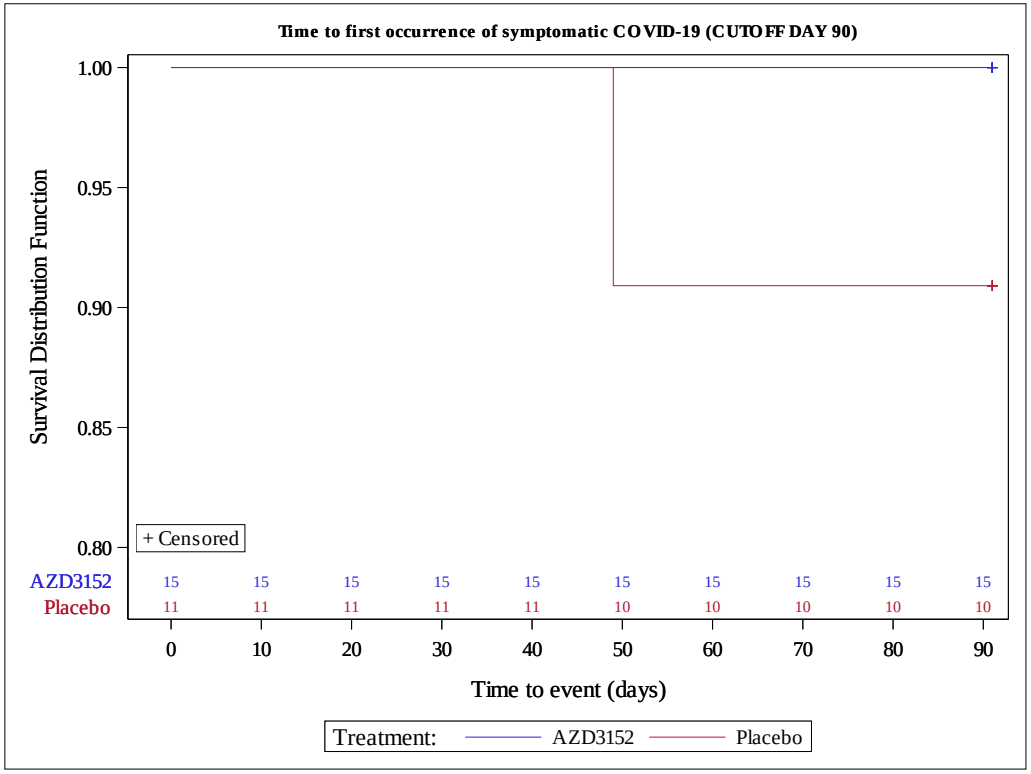
Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, Day 90, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of symptomatic COVID-19 (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup	AZD3152 (N=15)		Placebo (N=11)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		1/ 4 (25.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		1/ 5 (20.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		1/ 8 (12.5)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		1/ 8 (12.5)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		1/ 6 (16.7)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		1/ 9 (11.1)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Time to first occurrence of symptomatic COVID-19 (CUTOFF DAY 90)
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of symptomatic COVID-19
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (49.0, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

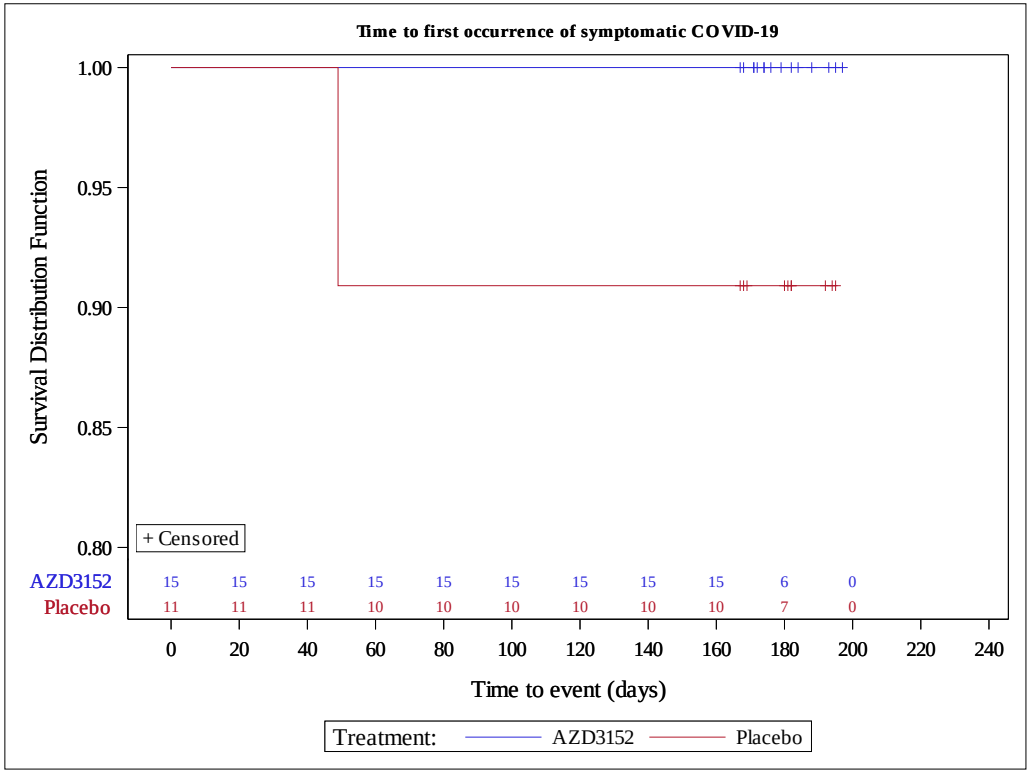
Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of symptomatic COVID-19 - Subgroup analysis
Full analysis Set

Subgroup	AZD3152 (N=15)		Placebo (N=11)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		1/ 4 (25.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		1/ 5 (20.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		1/ 8 (12.5)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		1/ 8 (12.5)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		1/ 6 (16.7)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		1/ 9 (11.1)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Time to first occurrence of symptomatic COVID-19
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of COVID-19 related hospitalization or death (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

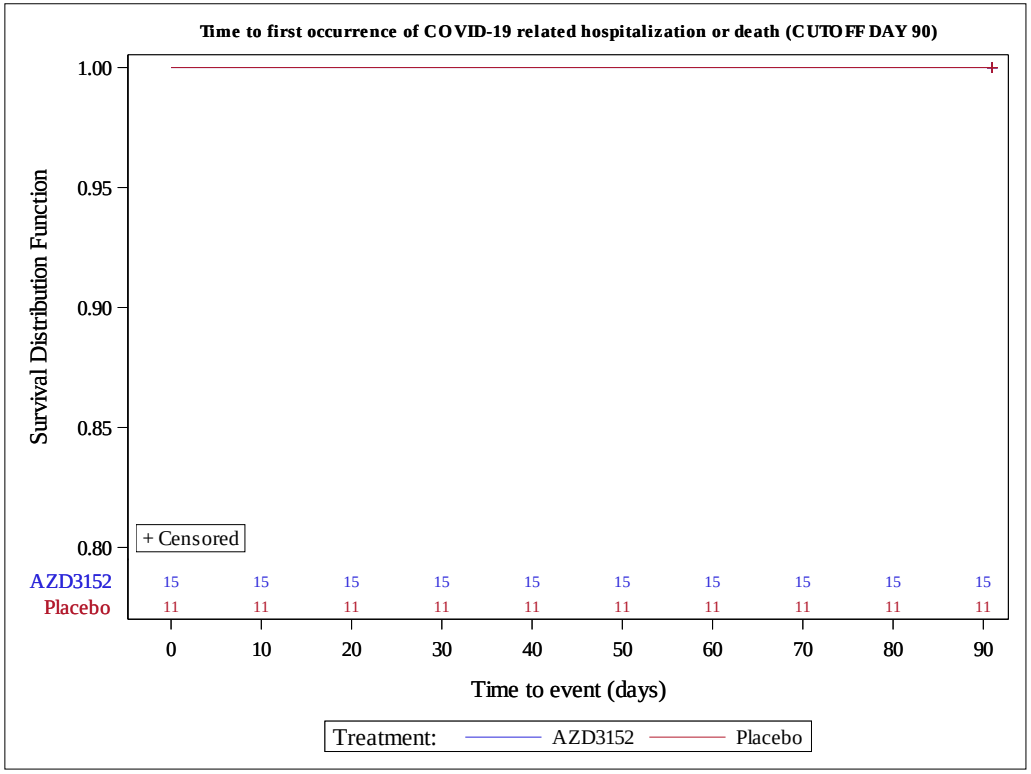
Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, Day 90, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of COVID-19 related hospitalization or death (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup	AZD3152 (N=15)		Placebo (N=11)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		0/ 4 (0.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		0/ 5 (0.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		0/ 8 (0.0)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		0/ 8 (0.0)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		0/ 6 (0.0)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		0/ 9 (0.0)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Time to first occurrence of COVID-19 related hospitalization or death (CUTOFF DAY 90)
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of COVID-19 related hospitalization or death
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Kaplan-Meier estimates of Time to Event (days) [1]		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Untratified analysis		
Hazard Ratio (95% CI) [2]	NE	
p-value [3]		

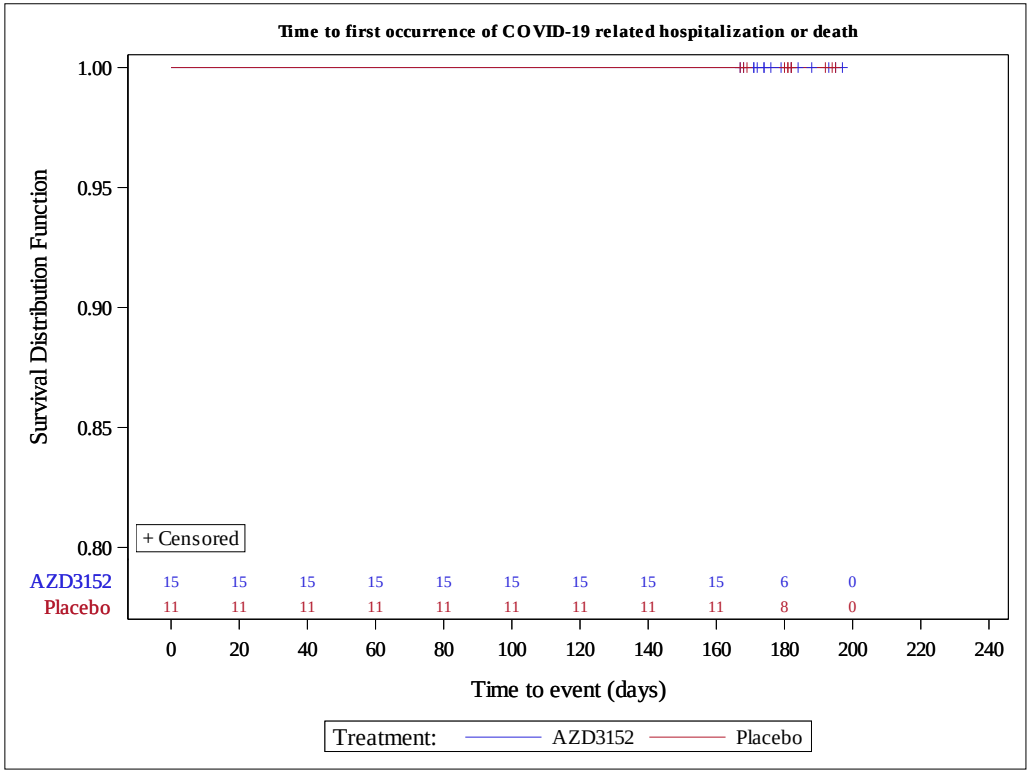
Follow-up time at risk starting from the first investigational product dose up to the event or censoring date.
Censoring date: min(Any COVID-19 preventive product, unblinding, death not related to COVID-19, early withdrawal, lost to follow-up, data cutoff)
[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Time to first occurrence of COVID-19 related hospitalization or death - Subgroup analysis
Full analysis Set

Subgroup	AZD3152 (N=15)		Placebo (N=11)		Unstratified analysis		Interaction
Level	n/ N (%)	Median (95% CI)[1]	n/ N (%)	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	p-Value[3]	p-Value[4]
Age							
< 60	0/ 7 (0.0)		0/ 7 (0.0)				
>= 60	0/ 8 (0.0)		0/ 4 (0.0)				
Sex							
Male	0/ 13 (0.0)		0/ 6 (0.0)				
Female	0/ 2 (0.0)		0/ 5 (0.0)				
BMI							
< 30kg/m^2	0/ 10 (0.0)		0/ 8 (0.0)				
>= 30kg/m^2	0/ 5 (0.0)		0/ 3 (0.0)				
Electrocardiogram (ECG) interpretation							
Normal	0/ 8 (0.0)		0/ 5 (0.0)				
Abnormal	0/ 5 (0.0)		0/ 3 (0.0)				
Solid organ transplant or hematopoietic stem cell transplant							
Yes	0/ 8 (0.0)		0/ 3 (0.0)				
No	0/ 7 (0.0)		0/ 8 (0.0)				
Active solid tumors or hematologic malignancies							
Yes	0/ 4 (0.0)		0/ 6 (0.0)				
No	0/ 11 (0.0)		0/ 5 (0.0)				
Taking immunsuppressive medicines							
Yes	0/ 3 (0.0)		0/ 2 (0.0)				
No	0/ 12 (0.0)		0/ 9 (0.0)				

[1] Based on the Brookmeyer and Crowley method.
[2] Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates reduction in hazard rate in favor of AZD3152 compared to Placebo.
[3] P-value based on Cox proportional hazards model.
[4] P-Value for interaction from Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction as covariates.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Kaplan Meier Plot of Time to first occurrence of COVID-19 related hospitalization or death
Full analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1]	NE	
p-value		
Relative Risk (95% CI) [2]	NE	
p-value		
Odds Ratio (95% CI) [2]	NE	
p-value		
Risk Difference (95% CI) [2]	NE	
p-value		

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1]	NE	
p-value		
Relative Risk (95% CI) [2]	NE	
p-value		
Odds Ratio (95% CI) [2]	NE	
p-value		
Risk Difference (95% CI) [2]	NE	
p-value		

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality - COVID-19 related (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1]	NE	
p-value		
Relative Risk (95% CI) [2]	NE	
p-value		
Odds Ratio (95% CI) [2]	NE	
p-value		
Risk Difference (95% CI) [2]	NE	
p-value		

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality - COVID-19 related (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality - COVID-19 related
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1]	NE	
p-value		
Relative Risk (95% CI) [2]	NE	
p-value		
Odds Ratio (95% CI) [2]	NE	
p-value		
Risk Difference (95% CI) [2]	NE	
p-value		

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of Overall Mortality - COVID-19 related - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1] **	0.70 (0.00, 27.40)	
p-value	0.4127	
Relative Risk (95% CI) [2]	0.25 (0.01, 5.62)	
p-value	0.3826	
Odds Ratio (95% CI) [2]	0.23 (0.01, 6.09)	
p-value	0.3761	
Risk Difference (95% CI) [2]	-9.09 (-26.08, 7.90)	
p-value	0.2943	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of symptomatic COVID-19 (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	1/ 4 (25.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	1/ 5 (20.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	1/ 8 (12.5)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	1/ 8 (12.5)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	1/ 6 (16.7)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	1/ 9 (11.1)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of symptomatic COVID-19
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1] **	0.69 (0.00, 26.94)	
p-value	0.4086	
Relative Risk (95% CI) [2]	0.25 (0.01, 5.62)	
p-value	0.3826	
Odds Ratio (95% CI) [2]	0.23 (0.01, 6.09)	
p-value	0.3761	
Risk Difference (95% CI) [2]	-9.09 (-26.08, 7.90)	
p-value	0.2943	

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of symptomatic COVID-19 - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	1/ 4 (25.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	1/ 5 (20.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	1/ 8 (12.5)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	1/ 8 (12.5)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	1/ 6 (16.7)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	1/ 9 (11.1)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of COVID-19 related hospitalization or death (CUTOFF DAY 90)
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1]	NE	
p-value		
Relative Risk (95% CI) [2]	NE	
p-value		
Odds Ratio (95% CI) [2]	NE	
p-value		
Risk Difference (95% CI) [2]	NE	
p-value		

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of COVID-19 related hospitalization or death (CUTOFF DAY 90) - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of COVID-19 related hospitalization or death
Full analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Poisson regression (95% CI) [1]	NE	
p-value		
Relative Risk (95% CI) [2]	NE	
p-value		
Odds Ratio (95% CI) [2]	NE	
p-value		
Risk Difference (95% CI) [2]	NE	
p-value		

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] Calculated using normal approximation (Wald).
NE: Not estimable; ** Exact Poisson regression with one-sided 97.5% confidence interval; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Analysis of Incidence of COVID-19 related hospitalization or death - Subgroup analysis
Full analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value [1]	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

[1] Poisson regression with robust variance, which includes study intervention as covariate, adjusts for follow-up time and patient-id in REPEAT statement.
[2] p-Value for interaction based on Cochran´s Q Test.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
* Exact Poisson regression
** Exact Poisson regression with one-sided 97.5% confidence interval
NE: Not estimable; I: Infinity

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	6 (40.0)	6 (54.5)
Number of censored subjects, n (%)	9 (60.0)	5 (45.5)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.73 (0.32, 1.67)	
p-value	0.4594	
Odds Ratio (95% CI) [1]	0.56 (0.12, 2.68)	
p-value	0.4640	
Risk Difference (95% CI) [1]	-14.55 (-53.02, 23.93)	
p-value	0.4587	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	1/ 7 (14.3)	5/ 7 (71.4)		
>= 60	5/ 8 (62.5)	1/ 4 (25.0)		
Sex				
Male	6/ 13 (46.2)	3/ 6 (50.0)		
Female	0/ 2 (0.0)	3/ 5 (60.0)		
BMI				
< 30kg/m^2	4/ 10 (40.0)	5/ 8 (62.5)		
>= 30kg/m^2	2/ 5 (40.0)	1/ 3 (33.3)		
Electrocardiogram (ECG) interpretation				
Normal	3/ 8 (37.5)	3/ 5 (60.0)		
Abnormal	2/ 5 (40.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	3/ 8 (37.5)	2/ 3 (66.7)		
No	3/ 7 (42.9)	4/ 8 (50.0)		
Active solid tumors or hematologic malignancies				
Yes	3/ 4 (75.0)	4/ 6 (66.7)		
No	3/ 11 (27.3)	2/ 5 (40.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	6/ 12 (50.0)	6/ 9 (66.7)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE excluding PTs related to underlying disease progression
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	6 (40.0)	6 (54.5)
Number of censored subjects, n (%)	9 (60.0)	5 (45.5)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.73 (0.32, 1.67)	
p-value	0.4594	
Odds Ratio (95% CI) [1]	0.56 (0.12, 2.68)	
p-value	0.4640	
Risk Difference (95% CI) [1]	-14.55 (-53.02, 23.93)	
p-value	0.4587	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE excluding PTs related to underlying disease progression - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	1/ 7 (14.3)	5/ 7 (71.4)		
>= 60	5/ 8 (62.5)	1/ 4 (25.0)		
Sex				
Male	6/ 13 (46.2)	3/ 6 (50.0)		
Female	0/ 2 (0.0)	3/ 5 (60.0)		
BMI				
< 30kg/m^2	4/ 10 (40.0)	5/ 8 (62.5)		
>= 30kg/m^2	2/ 5 (40.0)	1/ 3 (33.3)		
Electrocardiogram (ECG) interpretation				
Normal	3/ 8 (37.5)	3/ 5 (60.0)		
Abnormal	2/ 5 (40.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	3/ 8 (37.5)	2/ 3 (66.7)		
No	3/ 7 (42.9)	4/ 8 (50.0)		
Active solid tumors or hematologic malignancies				
Yes	3/ 4 (75.0)	4/ 6 (66.7)		
No	3/ 11 (27.3)	2/ 5 (40.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	6/ 12 (50.0)	6/ 9 (66.7)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AE
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	2 (18.2)
Number of censored subjects, n (%)	15 (100.0)	9 (81.8)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.15 (0.01, 2.84)	
p-value	0.2064	
Odds Ratio (95% CI) [1]	0.12 (0.01, 2.84)	
p-value	0.1904	
Risk Difference (95% CI) [1]	-18.18 (-40.97, 4.61)	
p-value	0.1179	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AE - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	2/ 7 (28.6)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	2/ 6 (33.3)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	1/ 8 (12.5)		
>= 30kg/m^2	0/ 5 (0.0)	1/ 3 (33.3)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	2/ 5 (40.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	1/ 3 (33.3)		
No	0/ 7 (0.0)	1/ 8 (12.5)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	1/ 6 (16.7)		
No	0/ 11 (0.0)	1/ 5 (20.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	2/ 9 (22.2)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	2 (18.2)
Number of censored subjects, n (%)	15 (100.0)	9 (81.8)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.15 (0.01, 2.84)	
p-value	0.2064	
Odds Ratio (95% CI) [1]	0.12 (0.01, 2.84)	
p-value	0.1904	
Risk Difference (95% CI) [1]	-18.18 (-40.97, 4.61)	
p-value	0.1179	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	2/ 7 (28.6)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	2/ 6 (33.3)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	1/ 8 (12.5)		
>= 30kg/m^2	0/ 5 (0.0)	1/ 3 (33.3)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	2/ 5 (40.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	1/ 3 (33.3)		
No	0/ 7 (0.0)	1/ 8 (12.5)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	1/ 6 (16.7)		
No	0/ 11 (0.0)	1/ 5 (20.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	2/ 9 (22.2)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AE
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	1 (6.7)	2 (18.2)
Number of censored subjects, n (%)	14 (93.3)	9 (81.8)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.37 (0.04, 3.55)	
p-value	0.3865	
Odds Ratio (95% CI) [1]	0.32 (0.03, 4.09)	
p-value	0.3816	
Risk Difference (95% CI) [1]	-11.52 (-37.57, 14.54)	
p-value	0.3864	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AE - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	2/ 7 (28.6)			
>= 60	1/ 8 (12.5)	0/ 4 (0.0)			
Sex					
Male	1/ 13 (7.7)	2/ 6 (33.3)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	1/ 10 (10.0)	1/ 8 (12.5)			
>= 30kg/m^2	0/ 5 (0.0)	1/ 3 (33.3)			
Electrocardiogram (ECG) interpretation					
Normal	1/ 8 (12.5)	2/ 5 (40.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	1/ 3 (33.3)			
No	1/ 7 (14.3)	1/ 8 (12.5)			
Active solid tumors or hematologic malignancies					
Yes	1/ 4 (25.0)	1/ 6 (16.7)			
No	0/ 11 (0.0)	1/ 5 (20.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	1/ 12 (8.3)	2/ 9 (22.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	1 (6.7)	2 (18.2)
Number of censored subjects, n (%)	14 (93.3)	9 (81.8)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.37 (0.04, 3.55)	
p-value	0.3865	
Odds Ratio (95% CI) [1]	0.32 (0.03, 4.09)	
p-value	0.3816	
Risk Difference (95% CI) [1]	-11.52 (-37.57, 14.54)	
p-value	0.3864	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	2/ 7 (28.6)			
>= 60	1/ 8 (12.5)	0/ 4 (0.0)			
Sex					
Male	1/ 13 (7.7)	2/ 6 (33.3)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	1/ 10 (10.0)	1/ 8 (12.5)			
>= 30kg/m^2	0/ 5 (0.0)	1/ 3 (33.3)			
Electrocardiogram (ECG) interpretation					
Normal	1/ 8 (12.5)	2/ 5 (40.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	1/ 3 (33.3)			
No	1/ 7 (14.3)	1/ 8 (12.5)			
Active solid tumors or hematologic malignancies					
Yes	1/ 4 (25.0)	1/ 6 (16.7)			
No	0/ 11 (0.0)	1/ 5 (20.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	1/ 12 (8.3)	2/ 9 (22.2)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Non-severe AE
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	5 (33.3)	6 (54.5)
Number of censored subjects, n (%)	10 (66.7)	5 (45.5)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.61 (0.25, 1.50)	
p-value	0.2815	
Odds Ratio (95% CI) [1]	0.42 (0.08, 2.06)	
p-value	0.2836	
Risk Difference (95% CI) [1]	-21.21 (-59.09, 16.67)	
p-value	0.2724	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Non-severe AE - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	1/ 7 (14.3)	5/ 7 (71.4)		
>= 60	4/ 8 (50.0)	1/ 4 (25.0)		
Sex				
Male	5/ 13 (38.5)	3/ 6 (50.0)		
Female	0/ 2 (0.0)	3/ 5 (60.0)		
BMI				
< 30kg/m^2	3/ 10 (30.0)	5/ 8 (62.5)		
>= 30kg/m^2	2/ 5 (40.0)	1/ 3 (33.3)		
Electrocardiogram (ECG) interpretation				
Normal	2/ 8 (25.0)	3/ 5 (60.0)		
Abnormal	2/ 5 (40.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	3/ 8 (37.5)	2/ 3 (66.7)		
No	2/ 7 (28.6)	4/ 8 (50.0)		
Active solid tumors or hematologic malignancies				
Yes	2/ 4 (50.0)	4/ 6 (66.7)		
No	3/ 11 (27.3)	2/ 5 (40.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	5/ 12 (41.7)	6/ 9 (66.7)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE leading to discontinuation of study treatment
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE leading to discontinuation of study treatment - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE leading to death
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE leading to death - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AESI
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AESI - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AESI
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AESI - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AESI
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AESI - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1]	 p-Value	Interaction p-Value [2]
Age					
< 60	0/ 7 (0.0)	0/ 7 (0.0)			
>= 60	0/ 8 (0.0)	0/ 4 (0.0)			
Sex					
Male	0/ 13 (0.0)	0/ 6 (0.0)			
Female	0/ 2 (0.0)	0/ 5 (0.0)			
BMI					
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)			
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)			
Electrocardiogram (ECG) interpretation					
Normal	0/ 8 (0.0)	0/ 5 (0.0)			
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)			
Solid organ transplant or hematopoietic stem cell transplant					
Yes	0/ 8 (0.0)	0/ 3 (0.0)			
No	0/ 7 (0.0)	0/ 8 (0.0)			
Active solid tumors or hematologic malignancies					
Yes	0/ 4 (0.0)	0/ 6 (0.0)			
No	0/ 11 (0.0)	0/ 5 (0.0)			
Taking immunsuppressive medicines					
Yes	0/ 3 (0.0)	0/ 2 (0.0)			
No	0/ 12 (0.0)	0/ 9 (0.0)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Non-severe AESI
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Non-severe AESI - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE related to COVID-19
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
p-value	0.3826	
Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
p-value	0.3761	
Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of AE related to COVID-19 - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	1/ 4 (25.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	1/ 5 (20.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	1/ 8 (12.5)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	1/ 8 (12.5)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	1/ 6 (16.7)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	1/ 9 (11.1)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AE related to COVID-19
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Serious AE related to COVID-19 - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AE related to COVID-19
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	15 (100.0)	11 (100.0)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	NE	
p-value		
Odds Ratio (95% CI) [1]	NE	
p-value		
Risk Difference (95% CI) [1]	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Severe AE related to COVID-19 - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	0/ 4 (0.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	0/ 5 (0.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	0/ 8 (0.0)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	0/ 8 (0.0)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	0/ 6 (0.0)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	0/ 9 (0.0)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Non-severe AE related to COVID-19
Safety analysis Set

	AZD3152 (N=15)	Placebo (N=11)
Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
Unstratified Analysis AZD3152 vs. Placebo		
Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
p-value	0.3826	
Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
p-value	0.3761	
Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of Non-severe AE related to COVID-19 - Subgroup analysis
Safety analysis Set

Subgroup Level	AZD3152 (N=15) n/ N (%)	Placebo (N=11) n/ N (%)	Analysis AZD3152 vs. Placebo Relative Risk (95% CI) [1] p-Value	Interaction p-Value [2]
Age				
< 60	0/ 7 (0.0)	0/ 7 (0.0)		
>= 60	0/ 8 (0.0)	1/ 4 (25.0)		
Sex				
Male	0/ 13 (0.0)	0/ 6 (0.0)		
Female	0/ 2 (0.0)	1/ 5 (20.0)		
BMI				
< 30kg/m^2	0/ 10 (0.0)	1/ 8 (12.5)		
>= 30kg/m^2	0/ 5 (0.0)	0/ 3 (0.0)		
Electrocardiogram (ECG) interpretation				
Normal	0/ 8 (0.0)	0/ 5 (0.0)		
Abnormal	0/ 5 (0.0)	0/ 3 (0.0)		
Solid organ transplant or hematopoietic stem cell transplant				
Yes	0/ 8 (0.0)	0/ 3 (0.0)		
No	0/ 7 (0.0)	1/ 8 (12.5)		
Active solid tumors or hematologic malignancies				
Yes	0/ 4 (0.0)	1/ 6 (16.7)		
No	0/ 11 (0.0)	0/ 5 (0.0)		
Taking immunsuppressive medicines				
Yes	0/ 3 (0.0)	0/ 2 (0.0)		
No	0/ 12 (0.0)	1/ 9 (11.1)		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
[1] Calculated using normal approximation (Wald).
[2] p-Value for interaction based on Cochran´s Q Test.
The table includes AEs with an onset date or after the date of study drug dose.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	2 (13.3)	2 (18.2)
	Number of censored subjects, n (%)	13 (86.7)	9 (81.8)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.73 (0.12, 4.43)	
	p-value	0.7354	
	Odds Ratio (95% CI) [1]	0.69 (0.08, 5.86)	
	p-value	0.7358	
	Risk Difference (95% CI) [1]	-4.85 (-33.40, 23.71)	
	p-value	0.7393	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations	Number of subjects with events, n (%)	1 (6.7)	3 (27.3)
	Number of censored subjects, n (%)	14 (93.3)	8 (72.7)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.24 (0.03, 2.05)	
	p-value	0.1939	
	Odds Ratio (95% CI) [1]	0.19 (0.02, 2.15)	
	p-value	0.1800	
	Risk Difference (95% CI) [1]	-20.61 (-49.80, 8.58)	
	p-value	0.1665	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	0 (0.0)	2 (18.2)
	Number of censored subjects, n (%)	15 (100.0)	9 (81.8)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.15 (0.01, 2.84)	
	p-value	0.2064	
	Odds Ratio (95% CI) [1]	0.12 (0.01, 2.84)	
	p-value	0.1904	
	Risk Difference (95% CI) [1]	-18.18 (-40.97, 4.61)	
	p-value	0.1179	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Injury, poisoning and procedural complications, PT: Radius fracture	Number of subjects with events, n (%)	0 (0.0)	2 (18.2)
	Number of censored subjects, n (%)	15 (100.0)	9 (81.8)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.15 (0.01, 2.84)	
	p-value	0.2064	
	Odds Ratio (95% CI) [1]	0.12 (0.01, 2.84)	
	p-value	0.1904	
	Risk Difference (95% CI) [1]	-18.18 (-40.97, 4.61)	
	p-value	0.1179	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	1 (6.7)	2 (18.2)
	Number of censored subjects, n (%)	14 (93.3)	9 (81.8)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.37 (0.04, 3.55)	
	p-value	0.3865	
	Odds Ratio (95% CI) [1]	0.32 (0.03, 4.09)	
	p-value	0.3816	
	Risk Difference (95% CI) [1]	-11.52 (-37.57, 14.54)	
	p-value	0.3864	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

AstraZeneca: Final
D7000C00001 NOVELLA
STIKO Covid-19 pre-exposition recommendation Population
Datacut: 11JUL2024
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations, PT: Necrotising ulcerative gingivostomatitis	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Injury, poisoning and procedural complications, PT: Radius fracture	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	1 (6.7)	1 (9.1)
	Number of censored subjects, n (%)	14 (93.3)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.73 (0.05, 10.49)	
	p-value	0.8193	
	Odds Ratio (95% CI) [1]	0.71 (0.04, 12.83)	
	p-value	0.8194	
	Risk Difference (95% CI) [1]	-2.42 (-23.59, 18.74)	
	p-value	0.8224	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Blood and lymphatic system disorders, PT: Febrile neutropenia	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Blood and lymphatic system disorders, PT: Leukopenia	Number of subjects with events, n (%)	1 (6.7)	0 (0.0)
	Number of censored subjects, n (%)	14 (93.3)	11 (100.0)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	2.25 (0.10, 50.54)	
	p-value	0.6095	
	Odds Ratio (95% CI) [1]	2.38 (0.09, 64.05)	
	p-value	0.6059	
	Risk Difference (95% CI) [1]	6.67 (-5.96, 19.29)	
	p-value	0.3006	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
NE: Not estimable

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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Number of subjects with events, n (%)	1 (6.7)	0 (0.0)
	Number of censored subjects, n (%)	14 (93.3)	11 (100.0)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	2.25 (0.10, 50.54)	
	p-value	0.6095	
	Odds Ratio (95% CI) [1]	2.38 (0.09, 64.05)	
	p-value	0.6059	
	Risk Difference (95% CI) [1]	6.67 (-5.96, 19.29)	
	p-value	0.3006	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations, PT: Necrotising ulcerative gingivostomatitis	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
	p-value	0.2943	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The table includes AEs with an onset date or after the date of study drug dose.
[1] Calculated using normal approximation (Wald).
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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
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Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
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Overall Summary of frequent Severe AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety analysis Set

		AZD3152 (N=15)	Placebo (N=11)
SOC: Injury, poisoning and procedural complications, PT: Radius fracture	Number of subjects with events, n (%)	0 (0.0)	1 (9.1)
	Number of censored subjects, n (%)	15 (100.0)	10 (90.9)
	Unstratified Analysis AZD3152 vs. Placebo		
	Relative Risk (95% CI) [1]	0.25 (0.01, 5.62)	
	p-value	0.3826	
	Odds Ratio (95% CI) [1]	0.23 (0.01, 6.09)	
	p-value	0.3761	
	Risk Difference (95% CI) [1]	-9.09 (-26.08, 7.90)	
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