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Dossier zur Nutzenbewertung gemäß § 35a SGB V

Etranacogen dezaparvovec (Hemgenix®)

CSL Behring GmbH

Modul 4 Anhang 4-G – Subgruppenanalysen (Sicherheit)

Hemgenix ist indiziert zur Behandlung von schwerer und mittelschwerer Hämophilie B (angeborener Faktor-IX-Mangel) bei erwachsenen Patienten ohne Faktor-IX-Inhibitoren in ihrer Vorgeschichte

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 28.04.2023

Inhaltsverzeichnis

1. UE unabhängig vom Schweregrad (Zeit bis zum ersten UE) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first AE with any severity of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	26 (65%)	1.9 (1.2, 3.2)	5.5 (2.8, —)	9.2 (6.2, —)
Post-Treament Month 0 - 24	40	40 (100%)	0.05 (0.03, 0.07)	0.11 (0.07, 0.26)	0.33 (0.20, 0.72)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first AE with any severity of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	11 (79%)	0.59 (0.26, 2.9)	3.9 (0.49, 5.9)	5.9 (2.9, —)
Post-Treament Month 0 - 24	14	14 (100%)	0.03 (0.03, 0.03)	0.03 (0.03, 0.10)	0.10 (0.03, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
19 [4.58, 78.76]	0

HR [95% CI] of Race: Non-white or not specified group	p.value
13 [1.7, 99.37]	0.013

Interaction as a ratio of HRs [95% CI]	p.value
0.68 [0.06, 8.18]	0.764

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

		The first AE with any severity of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first AE with any severity of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	10 (50%)	3.9 (0.07, 5.4)	6.6 (3.0, —)	— (—, —)
Post-Treament Month 0 - 24	20	20 (100%)	0.03 (0.03, 0.10)	0.11 (0.03, 0.23)	0.25 (0.13, 0.72)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first AE with any severity of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	27 (79%)	1.3 (0.49, 2.2)	3.0 (1.4, 5.9)	7.3 (5.6, —)
Post-Treament Month 0 - 24	34	34 (100%)	0.03 (0.03, 0.07)	0.07 (0.03, 0.26)	0.33 (0.10, 1.6)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
19 [2.54, 141.93]	0.004

HR [95% CI] of Region: Europe group	p.value
16 [3.83, 66.76]	0

Interaction as a ratio of HRs [95% CI]	p.value
1.19 [0.1, 13.99]	0.891

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first AE with any severity of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	30 (75%)	1.4 (0.59, 2.5)	3.3 (2.1, 5.8)	7.3 (5.0, —)
Post-Treament Month 0 - 24	40	40 (100%)	0.03 (0.03, 0.07)	0.08 (0.03, 0.16)	0.33 (0.10, 1.6)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first AE with any severity of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	7 (50%)	5.4 (0.43, 5.9)	7.0 (1.9, —)	— (5.9, —)
Post-Treament Month 0 - 24	14	14 (100%)	0.03 (0.03, 0.10)	0.10 (0.03, 0.23)	0.23 (0.10, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
12.33 [3.8, 40]	0

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474785.69 [0, Inf]	0.998

Interaction as a ratio of HRs [95% CI]	p.value
130984442.08 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first AE with any severity of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	29 (66%)	2.1 (0.59, 3.0)	5.5 (2.8, 7.3)	9.2 (6.2, —)
Post-Treament Month 0 - 24	44	44 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.16)	0.28 (0.13, 0.72)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first AE with any severity of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	8 (80%)	1.2 (0.43, 4.7)	3.4 (0.43, 5.8)	5.8 (2.0, —)
Post-Treament Month 0 - 24	10	10 (100%)	0.03 (0.03, 0.10)	0.08 (0.03, 0.33)	0.33 (0.07, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
14 [4.34, 45.17]	0

HR [95% CI] of Status of target joint at screening: Presence group	p.value
1615474794.7 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first AE with any severity of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	21 (64%)	3.2 (0.46, 5.4)	5.8 (4.7, —)	9.2 (6.2, —)
Post-Treament Month 0 - 24	33	33 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.26)	0.33 (0.16, 1.6)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first AE with any severity of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	16 (76%)	1.2 (0.43, 1.9)	2.1 (1.2, 5.0)	7.3 (2.5, —)
Post-Treament Month 0 - 24	21	21 (100%)	0.03 (0.03, 0.07)	0.07 (0.03, 0.16)	0.23 (0.07, 1.9)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
32 [4.37, 234.18]	0.001

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
9.5 [2.21, 40.78]	0.002

Interaction as a ratio of HRs [95% CI]	p.value
3.37 [0.29, 39.69]	0.335

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first AE with any severity of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	13 (62%)	3.0 (1.4, 4.9)	5.9 (3.0, —)	9.2 (6.0, —)
Post-Treament Month 0 - 24	21	21 (100%)	0.03 (0.03, 0.07)	0.10 (0.03, 0.16)	0.16 (0.10, 0.72)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first AE with any severity of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	24 (73%)	1.2 (0.43, 2.1)	3.4 (1.9, 5.8)	7.3 (5.5, —)
Post-Treament Month 0 - 24	33	33 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.26)	0.33 (0.20, 1.9)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
1615474784.83 [0, Inf]	0.998

HR [95% CI] of Hepatitis B or C: Yes group	p.value
10.33 [3.16, 33.8]	0

Interaction as a ratio of HRs [95% CI]	p.value
156336269.5 [0, Inf]	0.998

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first AE with any severity of Baseline Steatosis grade Category: <S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	19 (68%)	1.6 (0.43, 4.7)	5.5 (2.2, 7.3)	— (5.9, —)
Post-Treament Month 0 - 24	28	28 (100%)	0.03 (0.03, 0.07)	0.08 (0.03, 0.26)	0.34 (0.10, 4.3)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first AE with any severity of Baseline Steatosis grade Category: >=S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	8 (67%)	1.7 (0.26, 3.0)	4.3 (0.49, —)	— (3.0, —)
Post-Treament Month 0 - 24	12	12 (100%)	0.03 (0.03, 0.03)	0.05 (0.03, 0.30)	0.25 (0.03, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
13 [3.09, 54.77]	0

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
1615474783.83 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
124267291.06 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

2. UE unabhängig vom Schweregrad (Erstes Ereignis Infektionen und parasitäre Erkrankungen) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first Infections and Infestations with any severity - SOC level of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	14 (35%)	6.4 (2.1, 10)	10 (7.3, —)	— (10, —)
Post-Treament Month 0 - 24	40	29 (72%)	1.1 (0.33, 3.5)	8.6 (3.1, 18)	32 (17, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Infections and Infestations with any severity - SOC level of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	5 (36%)	5.8 (0.59, —)	— (4.9, —)	— (—, —)
Post-Treament Month 0 - 24	14	11 (79%)	0.46 (0.03, 2.3)	3.7 (0.10, 25)	25 (2.3, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
2 [0.9, 4.45]	0.09

HR [95% CI] of Race: Non-white or not specified group	p.value
3.5 [0.73, 16.85]	0.118

Interaction as a ratio of HRs [95% CI]	p.value
1.75 [0.3, 10.21]	0.534

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first Infections and Infestations with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first Infections and Infestations with any severity - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	6 (30%)	6.2 (2.1, —)	— (5.4, —)	— (—, —)
Post-Treament Month 0 - 24	20	12 (60%)	2.5 (0.10, 18)	23 (1.6, —)	32 (24, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Infections and Infestations with any severity - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	13 (38%)	6.0 (1.4, —)	10 (6.8, —)	10 (—, —)
Post-Treament Month 0 - 24	34	28 (82%)	0.79 (0.30, 2.3)	4.0 (1.1, 13)	18 (5.1, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
2.33 [0.6, 9.02]	0.22

HR [95% CI] of Region: Europe group	p.value
2.25 [0.98, 5.17]	0.056

Interaction as a ratio of HRs [95% CI]	p.value
1.04 [0.21, 5.08]	0.964

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Infections and Infestations with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	17 (42%)	5.8 (2.1, 6.9)	10 (6.8, —)	10 (—, —)
Post-Treament Month 0 - 24	40	29 (72%)	1.6 (0.30, 3.5)	8.6 (2.3, 20)	32 (16, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Infections and Infestations with any severity - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	2 (14%)	— (2.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	11 (79%)	0.95 (0.16, 3.4)	4.4 (0.36, 25)	25 (3.4, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
1.89 [0.84, 4.24]	0.123

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
4 [0.85, 18.84]	0.08

Interaction as a ratio of HRs [95% CI]	p.value
2.12 [0.37, 12.16]	0.4

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Infections and Infestations with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	14 (32%)	6.8 (2.9, 10)	10 (7.3, —)	— (10, —)
Post-Treament Month 0 - 24	44	33 (75%)	1.1 (0.30, 3.1)	5.3 (2.3, 20)	32 (18, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Infections and Infestations with any severity - SOC level of Status of target joint at screening: Presence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	5 (50%)	3.1 (1.2, —)	7.7 (1.2, —)	— (5.8, —)
Post-Treament Month 0 - 24	10	7 (70%)	0.79 (0.07, 9.3)	8.6 (0.07, —)	— (7.8, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
2.62 [1.16, 5.93]	0.02

HR [95% CI] of Status of target joint at screening: Presence group	p.value
1.33 [0.3, 5.96]	0.706

Interaction as a ratio of HRs [95% CI]	p.value
1.97 [0.36, 10.82]	0.436

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Infections and Infestations with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	12 (36%)	6.0 (4.7, —)	10 (6.8, —)	10 (—, —)
Post-Treament Month 0 - 24	33	24 (73%)	1.1 (0.16, 3.1)	9.3 (1.6, 20)	32 (18, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Infections and Infestations with any severity - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	7 (33%)	3.1 (0.59, —)	— (3.1, —)	— (—, —)
Post-Treament Month 0 - 24	21	16 (76%)	1.5 (0.07, 3.4)	4.9 (1.5, 22)	24 (5.1, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
2.14 [0.87, 5.26]	0.096

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
2.5 [0.78, 7.97]	0.121

Interaction as a ratio of HRs [95% CI]	p.value
0.86 [0.2, 3.71]	0.837

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Infections and Infestations with any severity - SOC level of Hepatitis B or C: No group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	8 (38%)	6.0 (1.4, —)	— (6.0, —)	— (—, —)
Post-Treament Month 0 - 24	21	16 (76%)	0.69 (0.03, 3.4)	9.3 (0.69, 25)	32 (18, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Infections and Infestations with any severity - SOC level of Hepatitis B or C: Yes group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	11 (33%)	6.9 (2.0, —)	10 (7.3, —)	10 (—, —)
Post-Treament Month 0 - 24	33	24 (73%)	1.1 (0.30, 2.3)	5.1 (1.6, 17)	— (13, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
3.33 [0.92, 12.11]	0.067

HR [95% CI] of Hepatitis B or C: Yes group	p.value
1.88 [0.79, 4.42]	0.151

Interaction as a ratio of HRs [95% CI]	p.value
1.78 [0.38, 8.37]	0.467

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Infections and Infestations with any severity - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	10 (36%)	5.7 (1.2, —)	— (6.9, —)	— (—, —)
Post-Treament Month 0 - 24	28	22 (79%)	1.0 (0.10, 2.3)	4.0 (1.1, 18)	24 (5.1, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Infections and Infestations with any severity - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	3 (25%)	8.1 (1.4, —)	— (5.8, —)	— (—, —)
Post-Treament Month 0 - 24	12	6 (50%)	2.8 (0.03, 24)	28 (0.10, —)	— (24, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
2.8 [1.01, 7.77]	0.048

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
0.71 [0.1, 5.18]	0.739

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

3. UE unabhängig vom Schweregrad (Erstes Ereignis Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen) – Subgruppenanalysen – Studie HOPE-B – Monat 24

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	9 (22%)	7.9 (3.4, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	40	29 (72%)	2.0 (0.46, 3.7)	6.3 (2.7, 19)	— (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Race: Non-white or not specified group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	3 (21%)	— (0.43, —)	— (5.7, —)	— (—, —)
Post-Treament Month 0 - 24	14	7 (50%)	12 (0.03, 29)	29 (1.1, —)	— (29, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
5 [1.71, 14.63]	0.003

HR [95% CI] of Race: Non-white or not specified group	p.value
1.5 [0.25, 8.98]	0.657

Interaction as a ratio of HRs [95% CI]	p.value
0.3 [0.04, 2.42]	0.258

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	4 (20%)	— (3.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	15 (75%)	1.1 (0.03, 6.1)	13 (1.1, 29)	29 (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	8 (24%)	7.9 (2.8, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	34	21 (62%)	2.2 (0.46, 5.6)	11 (2.7, —)	— (19, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
3 [0.81, 11.08]	0.099

HR [95% CI] of Region: Europe group	p.value
4.67 [1.34, 16.24]	0.015

Interaction as a ratio of HRs [95% CI]	p.value
0.64 [0.11, 3.91]	0.632

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	10 (25%)	7.3 (3.4, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	40	28 (70%)	1.4 (0.30, 3.7)	10 (3.7, 19)	29 (19, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	2 (14%)	— (0.43, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	8 (57%)	2.2 (0.89, 15)	19 (2.2, —)	— (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
4.25 [1.43, 12.63]	0.009

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
3 [0.61, 14.86]	0.178

Interaction as a ratio of HRs [95% CI]	p.value
0.71 [0.1, 4.89]	0.724

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	8 (18%)	7.9 (4.4, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	44	29 (66%)	2.2 (0.82, 4.3)	15 (3.7, 29)	29 (21, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	4 (40%)	5.0 (0.43, —)	— (0.43, —)	— (—, —)
Post-Treament Month 0 - 24	10	7 (70%)	0.46 (0.10, 12)	9.0 (0.10, —)	— (6.5, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
4.75 [1.62, 13.96]	0.005

HR [95% CI] of Status of target joint at screening: Presence group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
2.37 [0.32, 17.74]	0.399

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	6 (18%)	7.9 (4.4, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	33	20 (61%)	3.7 (0.30, 6.1)	17 (4.3, —)	— (23, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	6 (29%)	5.7 (0.43, —)	— (5.7, —)	— (—, —)
Post-Treament Month 0 - 24	21	16 (76%)	1.1 (0.03, 2.2)	8.4 (1.1, 19)	29 (12, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
4.33 [1.23, 15.21]	0.022

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
3.33 [0.92, 12.11]	0.067

Interaction as a ratio of HRs [95% CI]	p.value
1.3 [0.21, 7.87]	0.775

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	3 (14%)	— (2.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	13 (62%)	0.89 (0.03, 4.3)	15 (0.89, —)	— (17, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	9 (27%)	7.3 (1.2, —)	— (7.3, —)	— (7.9, —)
Post-Treament Month 0 - 24	33	23 (70%)	2.7 (0.82, 6.1)	12 (3.7, 23)	29 (19, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
4.5 [0.97, 20.83]	0.054

HR [95% CI] of Hepatitis B or C: Yes group	p.value
3.5 [1.15, 10.63]	0.027

Interaction as a ratio of HRs [95% CI]	p.value
1.29 [0.19, 8.53]	0.795

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	8 (29%)	7.3 (1.1, —)	7.9 (7.3, —)	— (7.9, —)
Post-Treament Month 0 - 24	28	18 (64%)	2.0 (0.46, 3.7)	6.3 (2.2, —)	— (14, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	1 (8.3%)	— (3.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	12	5 (42%)	9.5 (0.03, 29)	29 (0.30, —)	— (29, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
5 [1.45, 17.27]	0.011

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
3 [0.31, 28.84]	0.341

Interaction as a ratio of HRs [95% CI]	p.value
0.6 [0.05, 7.92]	0.698

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Musculoskeletal and Connective Tissue Disorders with any severity - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

4. UE unabhängig vom Schweregrad (Erstes Ereignis Erkrankungen des Gastrointestinaltrakts) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first Gastrointestinal Disorders with any severity - SOC level of Race: White group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	4 (10%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	19 (48%)	3.4 (0.16, 9.3)	— (5.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Gastrointestinal Disorders with any severity - SOC level of Race: Non-white or not specified group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	3 (21%)	— (0.49, —)	— (5.8, —)	— (—, —)
Post-Treament Month 0 - 24	14	7 (50%)	2.9 (0.03, 24)	26 (2.8, —)	— (24, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
7.5 [1.72, 32.8]	0.007

HR [95% CI] of Race: Non-white or not specified group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
0.27 [0.03, 2.53]	0.249

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first Gastrointestinal Disorders with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first Gastrointestinal Disorders with any severity - SOC level of Region: USA group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	12 (60%)	3.1 (0.13, 12)	19 (2.8, —)	— (19, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Gastrointestinal Disorders with any severity - SOC level of Region: Europe group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	7 (21%)	— (3.2, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	14 (41%)	3.9 (0.07, 19)	— (6.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1615474788.33 [0, Inf]	0.999

HR [95% CI] of Region: Europe group	p.value
2.75 [0.88, 8.64]	0.083

Interaction as a ratio of HRs [95% CI]	p.value
587445377.57 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Gastrointestinal Disorders with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	7 (18%)	— (4.9, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	19 (48%)	3.4 (0.16, 18)	— (9.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Gastrointestinal Disorders with any severity - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	7 (50%)	3.4 (0.03, 19)	24 (2.2, —)	— (19, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
3.25 [1.06, 9.97]	0.039

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474789.85 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
497069166.11 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Gastrointestinal Disorders with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	6 (14%)	— (5.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	20 (45%)	3.4 (0.20, 9.3)	— (5.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Gastrointestinal Disorders with any severity - SOC level of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	1 (10%)	— (3.1, —)	— (3.1, —)	— (—, —)
Post-Treament Month 0 - 24	10	6 (60%)	0.36 (0.03, 18)	18 (0.03, —)	— (18, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
4 [1.34, 11.96]	0.013

HR [95% CI] of Status of target joint at screening: Presence group	p.value
594299951.89 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Gastrointestinal Disorders with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	3 (9.1%)	— (5.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	14 (42%)	4.1 (0.20, 19)	— (6.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Gastrointestinal Disorders with any severity - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	4 (19%)	— (0.49, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	12 (57%)	2.2 (0.03, 9.3)	18 (2.2, —)	— (19, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
11 [1.42, 85.2]	0.022

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
2.67 [0.71, 10.05]	0.147

Interaction as a ratio of HRs [95% CI]	p.value
4.12 [0.36, 47.3]	0.255

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Gastrointestinal Disorders with any severity - SOC level of Hepatitis B or C: No group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	3 (14%)	— (3.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	11 (52%)	3.4 (0.03, 18)	24 (3.4, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Gastrointestinal Disorders with any severity - SOC level of Hepatitis B or C: Yes group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	4 (12%)	— (4.9, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	15 (45%)	3.9 (0.07, 12)	— (6.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
8 [1, 63.96]	0.05

HR [95% CI] of Hepatitis B or C: Yes group	p.value
3.67 [1.02, 13.14]	0.046

Interaction as a ratio of HRs [95% CI]	p.value
2.18 [0.19, 25.02]	0.531

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Gastrointestinal Disorders with any severity - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	1 (3.6%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	28	13 (46%)	5.4 (0.03, 19)	— (9.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Gastrointestinal Disorders with any severity - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	4 (33%)	4.5 (0.49, —)	— (2.9, —)	— (—, —)
Post-Treament Month 0 - 24	12	6 (50%)	1.5 (0.03, 3.4)	16 (0.16, —)	— (3.4, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
8 [1, 63.96]	0.05

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
3 [0.61, 14.86]	0.178

Interaction as a ratio of HRs [95% CI]	p.value
0.38 [0.03, 5.17]	0.464

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

5. UE unabhängig vom Schweregrad (Erstes Ereignis Allgemeine Erkrankungen und Beschwerden am Verabreichungsort) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	2 (5.0%)	— (8.0, —)	— (8.0, —)	— (—, —)
Post-Treament Month 0 - 24	40	25 (62%)	0.10 (0.03, 0.33)	1.3 (0.26, —)	— (6.7, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	5 (36%)	0.10 (0.03, —)	— (0.07, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
25 [3.39, 184.5]	0.002

HR [95% CI] of Race: Non-white or not specified group	p.value
1615474790.9 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
64618991.64 [0, Inf]	0.999

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	11 (55%)	0.26 (0.03, 2.4)	7.9 (0.26, —)	— (9.0, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	2 (5.9%)	— (8.0, —)	— (8.0, —)	— (—, —)
Post-Treament Month 0 - 24	34	19 (56%)	0.10 (0.07, 0.43)	1.3 (0.10, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1615474787.01 [0, Inf]	0.999

HR [95% CI] of Region: Europe group	p.value
19 [2.54, 141.93]	0.004

Interaction as a ratio of HRs [95% CI]	p.value
85024988.79 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	2 (5.0%)	— (8.0, —)	— (8.0, —)	— (—, —)
Post-Treament Month 0 - 24	40	21 (52%)	0.10 (0.03, 0.43)	2.0 (0.26, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	9 (64%)	0.10 (0.03, 1.5)	4.1 (0.10, —)	— (1.5, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
21 [2.82, 156.12]	0.003

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474787.78 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
76927370.85 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between

	The first General Disorders and Administration Site Conditions with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	2 (4.5%)	— (8.0, —)	— (8.0, —)	— (—, —)
Post-Treament Month 0 - 24	44	25 (57%)	0.10 (0.03, 0.26)	2.0 (0.26, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Status of target joint at screening: Presence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	10	5 (50%)	0.46 (0.03, —)	14 (0.03, —)	— (1.1, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
25 [1.48, 422.24]	0.026

HR [95% CI] of Status of target joint at screening: Presence group	p.value
1615474862.62 [218897877.36, 11922267421.17]	0

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, 0]	0

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	1 (3.0%)	— (8.0, —)	— (8.0, —)	— (—, —)
Post-Treament Month 0 - 24	33	19 (58%)	0.10 (0.03, 0.26)	1.5 (0.26, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	1 (4.8%)	— (5.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	11 (52%)	0.26 (0.03, 1.1)	9.0 (0.26, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
1615474785.27 [0, Inf]	0.998

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
11 [1.42, 85.2]	0.022

Interaction as a ratio of HRs [95% CI]	p.value
146861344.12 [0, Inf]	0.998

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between

	The first General Disorders and Administration Site Conditions with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	1 (4.8%)	9.1 (8.0, —)	— (8.0, —)	— (8.0, —)
Post-Treament Month 0 - 24	21	11 (52%)	0.10 (0.03, 0.53)	9.0 (0.10, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	1 (3.0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	19 (58%)	0.10 (0.07, 0.33)	1.6 (0.26, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
1615474787.01 [0, Inf]	0.999

HR [95% CI] of Hepatitis B or C: Yes group	p.value
19 [2.54, 141.93]	0.004

Interaction as a ratio of HRs [95% CI]	p.value
85024988.79 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	1 (3.6%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	28	17 (61%)	0.10 (0.03, 0.46)	1.6 (0.26, —)	— (6.7, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first General Disorders and Administration Site Conditions with any severity - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	12	6 (50%)	0.18 (0.03, 0.59)	16 (0.07, —)	— (0.59, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
17 [2.26, 127.74]	0.006

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
1615474789.65 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
95027928.8 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

6. UE unabhängig vom Schweregrad (Erstes Ereignis Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen) – Subgruppenanalysen – Studie HOPE-B – Monat 24

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	4 (10%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	19 (48%)	11 (1.3, 24)	28 (21, —)	— (28, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Race: Non-white or not specified group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	6 (43%)	5.8 (0.03, —)	— (1.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
3.5 [0.73, 16.85]	0.118

HR [95% CI] of Race: Non-white or not specified group	p.value
1615474793.02 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
461564226.58 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	1 (5.0%)	— (1.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	10 (50%)	11 (0.23, 24)	30 (9.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	3 (8.8%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	15 (44%)	8.3 (1.3, 27)	28 (22, —)	— (28, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1615474793.02 [0, Inf]	0.999

HR [95% CI] of Region: Europe group	p.value
3.5 [0.73, 16.85]	0.118

Interaction as a ratio of HRs [95% CI]	p.value
461564226.58 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	3 (7.5%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	19 (48%)	7.9 (1.3, 23)	28 (21, —)	— (28, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	1 (7.1%)	— (1.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	6 (43%)	12 (0.23, —)	— (8.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
4.5 [0.97, 20.83]	0.054

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474783.47 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
358994396.33 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	3 (6.8%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	19 (43%)	12 (1.1, 24)	28 (22, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	1 (10%)	— (0.72, —)	— (0.72, —)	— (—, —)
Post-Treament Month 0 - 24	10	6 (60%)	1.3 (0.79, 24)	20 (0.79, —)	— (16, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
8 [1, 63.96]	0.05

HR [95% CI] of Status of target joint at screening: Presence group	p.value
3 [0.31, 28.84]	0.341

Interaction as a ratio of HRs [95% CI]	p.value
2.67 [0.12, 57.62]	0.532

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	2 (6.1%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	16 (48%)	12 (1.5, 24)	28 (22, —)	— (28, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	2 (9.5%)	— (0.72, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	9 (43%)	1.3 (0.03, 22)	— (1.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
6 [0.72, 49.84]	0.097

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
5 [0.58, 42.8]	0.142

Interaction as a ratio of HRs [95% CI]	p.value
1.2 [0.06, 24.47]	0.906

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	1 (4.8%)	— (1.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	13 (62%)	9.7 (0.23, 23)	24 (9.7, —)	28 (27, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	3 (9.1%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	12 (36%)	12 (0.79, —)	— (21, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
1615474790.89 [0, Inf]	0.999

HR [95% CI] of Hepatitis B or C: Yes group	p.value
3 [0.61, 14.86]	0.178

Interaction as a ratio of HRs [95% CI]	p.value
538491596.96 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	4 (14%)	— (1.8, —)	— (7.3, —)	— (—, —)
Post-Treament Month 0 - 24	28	16 (57%)	4.3 (0.23, 16)	23 (8.3, —)	— (28, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Injury, Poisoning and Procedural Complications with any severity - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	12	4 (33%)	7.7 (0.03, —)	— (1.5, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
3.5 [0.73, 16.85]	0.118

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
1615474783.52 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
461564223.86 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

7. UE unabhängig vom Schweregrad (Erstes Ereignis Erkrankungen der Atemwege, des Brustraums und Mediastinums) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	3 (7.5%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	12 (30%)	6.2 (1.2, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	3 (21%)	9.0 (0.26, —)	9.0 (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	14	7 (50%)	1.8 (0.07, 24)	27 (0.62, —)	— (24, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
5.5 [1.22, 24.81]	0.027

HR [95% CI] of Race: Non-white or not specified group	p.value
1.33 [0.3, 5.96]	0.706

Interaction as a ratio of HRs [95% CI]	p.value
0.24 [0.03, 2.03]	0.191

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	3 (15%)	9.0 (2.0, —)	9.0 (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	20	5 (25%)	30 (1.1, —)	— (24, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	3 (8.8%)	— (6.2, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	14 (41%)	4.3 (0.46, 7.2)	— (4.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1.5 [0.25, 8.98]	0.657

HR [95% CI] of Region: Europe group	p.value
4 [1.13, 14.17]	0.032

Interaction as a ratio of HRs [95% CI]	p.value
0.38 [0.04, 3.36]	0.38

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	5 (12%)	9.0 (6.2, —)	— (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	40	12 (30%)	8.0 (1.8, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	1 (7.1%)	— (5.5, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	7 (50%)	1.2 (0.59, 6.3)	17 (1.1, —)	— (6.3, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
1.6 [0.52, 4.89]	0.41

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474788.92 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
1009671743.08 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	4 (9.1%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	15 (34%)	5.5 (1.1, —)	— (24, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	2 (20%)	9.0 (2.0, —)	9.0 (2.0, —)	9.0 (—, —)
Post-Treament Month 0 - 24	10	4 (40%)	4.3 (0.33, —)	— (0.33, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
3.67 [1.02, 13.14]	0.046

HR [95% CI] of Status of target joint at screening: Presence group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
1.83 [0.22, 15.33]	0.576

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	4 (12%)	— (5.5, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	13 (39%)	4.6 (1.1, 24)	— (6.0, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	2 (9.5%)	9.0 (2.0, —)	— (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	21	6 (29%)	8.8 (0.07, —)	— (8.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
3.67 [1.02, 13.14]	0.046

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
1.83 [0.22, 15.33]	0.576

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Hepatitis B or C: No group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	1 (4.8%)	— (2.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	7 (33%)	6.0 (0.62, —)	— (6.0, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first Respiratory, Thoracic and Mediastinal Disorders with any severity - SOC level of Hepatitis B or C: Yes group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	5 (15%)	9.0 (5.5, —)	9.0 (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	33	12 (36%)	4.3 (0.33, —)	— (7.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
6 [0.72, 49.84]	0.097

HR [95% CI] of Hepatitis B or C: Yes group	p.value
2.25 [0.69, 7.31]	0.177

Interaction as a ratio of HRs [95% CI]	p.value
2.67 [0.24, 30.07]	0.427

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

8. UE unabhängig vom Schweregrad (Untersuchungen) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first Investigations with any severity - SOC level in Race: White group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	17 (42%)	17 (42%)
No	0 (0%)	23 (57%)	23 (57%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
18 [2.535, 127.788]	0.004	35 [2.105, 582.032]	0.013

A contingency table for The first Investigations with any severity - SOC level in Race: Non-white or not specified group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	5 (36%)	5 (36%)
No	0 (0%)	9 (64%)	9 (64%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
6 [0.845, 42.596]	0.073	11 [0.608, 198.941]	0.104

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
3.18	0.529

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (70%)	14 (70%)
No	0 (0%)	6 (30%)	6 (30%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first Investigations with any severity - SOC level in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	8 (24%)	8 (24%)
No	0 (0%)	26 (76%)	26 (76%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
9 [1.268, 63.894]	0.028	17 [0.981, 294.545]	0.051

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
1.71	0.492

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Lead-in Bleed count
Category: >=1 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	15 (38%)	15 (38%)
No	0 (0%)	25 (62%)	25 (62%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
16 [2.254, 113.589]	0.006	31 [1.855, 518.116]	0.017

A contingency table for The first Investigations with any severity - SOC level in Lead-in Bleed count
Category: 0 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (50%)	7 (50%)
No	0 (0%)	7 (50%)	7 (50%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
2.07	0.798

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	19 (43%)	19 (43%)
No	0 (0%)	25 (57%)	25 (57%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
20 [2.817, 141.987]	0.003	39 [2.355, 645.956]	0.011

A contingency table for The first Investigations with any severity - SOC level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	3 (30%)	3 (30%)
No	0 (0%)	7 (70%)	7 (70%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
4 [0.563, 28.397]	0.166	7 [0.362, 135.524]	0.199

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5.57	0.325

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Baseline Nab Titer category: Negative group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	13 (39%)	13 (39%)
No	0 (0%)	20 (61%)	20 (61%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
14 [1.972, 99.391]	0.008	27 [1.605, 454.21]	0.022

A contingency table for The first Investigations with any severity - SOC level in Baseline Nab Titer category: Positive group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	9 (43%)	9 (43%)
No	0 (0%)	12 (57%)	12 (57%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
10 [1.409, 70.993]	0.021	19 [1.106, 326.459]	0.042

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
1.42	0.885

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Hepatitis B or C: No group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	9 (43%)	9 (43%)
No	0 (0%)	12 (57%)	12 (57%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
10 [1.409, 70.993]	0.021	19 [1.106, 326.459]	0.042

A contingency table for The first Investigations with any severity - SOC level in Hepatitis B or C: Yes group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	13 (39%)	13 (39%)
No	0 (0%)	20 (61%)	20 (61%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
14 [1.972, 99.391]	0.008	27 [1.605, 454.21]	0.022

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (No vs. Yes)	p.value of the interaction test
0.7	0.885

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Baseline Steatosis grade Category: <S2 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (39%)	11 (39%)
No	0 (0%)	17 (61%)	17 (61%)
Total	0 (0%)	28 (100%)	28 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

A contingency table for The first Investigations with any severity - SOC level in Baseline Steatosis grade Category: >=S2 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (33%)	4 (33%)
No	0 (0%)	8 (67%)	8 (67%)
Total	0 (0%)	12 (100%)	12 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (<S2 vs. >=S2)	p.value of the interaction test
2.56	0.619

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Race: White group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	16 (40%)	16 (40%)
No	0 (0%)	24 (60%)	24 (60%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
17 [2.395, 120.689]	0.005	33 [1.98, 550.073]	0.015

A contingency table for The first Investigations with any severity - SOC level in Race: Non-white or not specified group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	5 (36%)	5 (36%)
No	0 (0%)	9 (64%)	9 (64%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
6 [0.845, 42.596]	0.073	11 [0.608, 198.941]	0.104

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
3	0.563

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Region: USA group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	13 (65%)	13 (65%)
No	0 (0%)	7 (35%)	7 (35%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
14 [1.972, 99.391]	0.008	27 [1.605, 454.21]	0.022

A contingency table for The first Investigations with any severity - SOC level in Region: Europe group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	8 (24%)	8 (24%)
No	0 (0%)	26 (76%)	26 (76%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
9 [1.268, 63.894]	0.028	17 [0.981, 294.545]	0.051

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
1.59	0.561

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Lead-in Bleed count Category: >=1 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (35%)	14 (35%)
No	0 (0%)	26 (65%)	26 (65%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first Investigations with any severity - SOC level in Lead-in Bleed count Category: 0 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (50%)	7 (50%)
No	0 (0%)	7 (50%)	7 (50%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
1.93	0.838

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	18 (41%)	18 (41%)
No	0 (0%)	26 (59%)	26 (59%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
19 [2.676, 134.887]	0.003	37 [2.23, 613.993]	0.012

A contingency table for The first Investigations with any severity - SOC level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	3 (30%)	3 (30%)
No	0 (0%)	7 (70%)	7 (70%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
4 [0.563, 28.397]	0.166	7 [0.362, 135.524]	0.199

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5.29	0.351

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Baseline Nab Titer category: Negative group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (36%)	12 (36%)
No	0 (0%)	21 (64%)	21 (64%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Investigations with any severity - SOC level in Baseline Nab Titer category: Positive group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	9 (43%)	9 (43%)
No	0 (0%)	12 (57%)	12 (57%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
10 [1.409, 70.993]	0.021	19 [1.106, 326.459]	0.042

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
1.32	0.933

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Hepatitis B or C: No group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	9 (43%)	9 (43%)
No	0 (0%)	12 (57%)	12 (57%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
10 [1.409, 70.993]	0.021	19 [1.106, 326.459]	0.042

A contingency table for The first Investigations with any severity - SOC level in Hepatitis B or C: Yes group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (36%)	12 (36%)
No	0 (0%)	21 (64%)	21 (64%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (No vs. Yes)	p.value of the interaction test
0.76	0.933

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Investigations with any severity - SOC level in Baseline Steatosis grade Category: <S2 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (36%)	10 (36%)
No	0 (0%)	18 (64%)	18 (64%)
Total	0 (0%)	28 (100%)	28 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first Investigations with any severity - SOC level in Baseline Steatosis grade Category: >=S2 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (33%)	4 (33%)
No	0 (0%)	8 (67%)	8 (67%)
Total	0 (0%)	12 (100%)	12 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (<S2 vs. >=S2)	p.value of the interaction test
2.33	0.671

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

9. UE unabhängig vom Schweregrad (Erstes Ereignis Arthralgie) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first Arthralgia with any severity - PT level of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	4 (10%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	40	15 (38%)	4.8 (0.82, —)	— (15, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Arthralgia with any severity - PT level of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	4 (29%)	19 (1.1, —)	— (12, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
6 [1.34, 26.81]	0.019

HR [95% CI] of Race: Non-white or not specified group	p.value
594300001.54 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
99050000.26 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first Arthralgia with any severity - PT level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first Arthralgia with any severity - PT level of Region: USA group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	9 (45%)	4.8 (0.03, 21)	— (4.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Arthralgia with any severity - PT level of Region: Europe group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	4 (12%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	34	10 (29%)	10 (1.1, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1615474789.87 [0, Inf]	0.999

HR [95% CI] of Region: Europe group	p.value
3.5 [0.73, 16.85]	0.118

Interaction as a ratio of HRs [95% CI]	p.value
461564225.68 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Arthralgia with any severity - PT level of Lead-in Bleed count Category: >=1 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	3 (7.5%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	40	15 (38%)	6.5 (0.82, —)	— (19, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Arthralgia with any severity - PT level of Lead-in Bleed count Category: 0 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	1 (7.1%)	— (5.6, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	4 (29%)	15 (1.2, —)	— (5.4, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
10 [1.28, 78.12]	0.028

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
3 [0.31, 28.84]	0.341

Interaction as a ratio of HRs [95% CI]	p.value
0.3 [0.01, 6.38]	0.44

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Arthralgia with any severity - PT level of Status of target joint at screening: Absence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	3 (6.8%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	44	16 (36%)	5.5 (1.1, —)	— (19, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Arthralgia with any severity - PT level of Status of target joint at screening: Presence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	1 (10%)	— (1.1, —)	— (1.1, —)	— (—, —)
Post-Treament Month 0 - 24	10	3 (30%)	12 (0.46, —)	— (0.46, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
6 [1.34, 26.81]	0.019

HR [95% CI] of Status of target joint at screening: Presence group	p.value
594299953.28 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Arthralgia with any severity - PT level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	2 (6.1%)	— (8.6, —)	— (8.6, —)	— (8.6, —)
Post-Treament Month 0 - 24	33	11 (33%)	10 (2.2, —)	— (21, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Arthralgia with any severity - PT level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	2 (9.5%)	— (1.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	8 (38%)	1.2 (0.03, —)	— (1.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
3.5 [0.38, 32.3]	0.269

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
1615474915.64 [335599013.1, 7776420970.26]	0

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, 0]	0

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first Arthralgia with any severity - PT level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	10 (48%)	4.3 (0.03, 15)	— (4.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first Arthralgia with any severity - PT level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	4 (12%)	8.6 (5.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	33	9 (27%)	19 (1.1, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
1615474788.33 [0, Inf]	0.999

HR [95% CI] of Hepatitis B or C: Yes group	p.value
2.5 [0.49, 12.89]	0.273

Interaction as a ratio of HRs [95% CI]	p.value
646189915.33 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

10. UE unabhängig vom Schweregrad (Ermüdung) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first Fatigue with any severity - PT level in Race: White group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (35%)	14 (35%)
No	0 (0%)	26 (65%)	26 (65%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first Fatigue with any severity - PT level in Race: Non-white or not specified group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	0 (0%)	0 (0%)
No	0 (0%)	14 (100%)	14 (100%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1 [0.141, 7.099]	1	1 [0.02, 50.4]	1

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
29	0.039

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Fatigue with any severity - PT level in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (10%)	2 (10%)
No	0 (0%)	18 (90%)	18 (90%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

A contingency table for The first Fatigue with any severity - PT level in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (35%)	12 (35%)
No	0 (0%)	22 (65%)	22 (65%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.2	0.334

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Fatigue with any severity - PT level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (27%)	12 (27%)
No	0 (0%)	32 (73%)	32 (73%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Fatigue with any severity - PT level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (20%)	2 (20%)
No	0 (0%)	8 (80%)	8 (80%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5	0.397

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Fatigue with any severity - PT level in Race: White group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (35%)	14 (35%)
No	0 (0%)	26 (65%)	26 (65%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first Fatigue with any severity - PT level in Race: Non-white or not specified group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	0 (0%)	0 (0%)
No	0 (0%)	14 (100%)	14 (100%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1 [0.141, 7.099]	1	1 [0.02, 50.4]	1

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
29	0.039

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Fatigue with any severity - PT level in Region: USA group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (10%)	2 (10%)
No	0 (0%)	18 (90%)	18 (90%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

A contingency table for The first Fatigue with any severity - PT level in Region: Europe group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (35%)	12 (35%)
No	0 (0%)	22 (65%)	22 (65%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.2	0.334

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Fatigue with any severity - PT level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (27%)	12 (27%)
No	0 (0%)	32 (73%)	32 (73%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Fatigue with any severity - PT level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (20%)	2 (20%)
No	0 (0%)	8 (80%)	8 (80%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5	0.397

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

11. UE unabhängig vom Schweregrad (Kopfschmerzen) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first Headache with any severity - PT level in Race: White group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (25%)	10 (25%)
No	0 (0%)	30 (75%)	30 (75%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first Headache with any severity - PT level in Race: Non-white or not specified group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	6 (43%)	6 (43%)
No	0 (0%)	8 (57%)	8 (57%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
7 [0.986, 49.695]	0.051	13 [0.732, 230.775]	0.08

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
1.62	0.913

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	6 (30%)	6 (30%)
No	0 (0%)	14 (70%)	14 (70%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
7 [0.986, 49.695]	0.051	13 [0.732, 230.775]	0.08

A contingency table for The first Headache with any severity - PT level in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (29%)	10 (29%)
No	0 (0%)	24 (71%)	24 (71%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.62	0.82

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Lead-in Bleed count Category: >=1 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (28%)	11 (28%)
No	0 (0%)	29 (72%)	29 (72%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

A contingency table for The first Headache with any severity - PT level in Lead-in Bleed count Category: 0 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	5 (36%)	5 (36%)
No	0 (0%)	9 (64%)	9 (64%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
6 [0.845, 42.596]	0.073	11 [0.608, 198.941]	0.104

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
2.09	0.762

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (27%)	12 (27%)
No	0 (0%)	32 (73%)	32 (73%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Headache with any severity - PT level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (40%)	4 (40%)
No	0 (0%)	6 (60%)	6 (60%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
2.78	0.679

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Baseline Nab Titer category: Negative group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (36%)	12 (36%)
No	0 (0%)	21 (64%)	21 (64%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Headache with any severity - PT level in Baseline Nab Titer category: Positive group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (19%)	4 (19%)
No	0 (0%)	17 (81%)	17 (81%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
2.78	0.54

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Race: White group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (25%)	10 (25%)
No	0 (0%)	30 (75%)	30 (75%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first Headache with any severity - PT level in Race: Non-white or not specified group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	6 (43%)	6 (43%)
No	0 (0%)	8 (57%)	8 (57%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
7 [0.986, 49.695]	0.051	13 [0.732, 230.775]	0.08

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
1.62	0.913

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Region: USA group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	6 (30%)	6 (30%)
No	0 (0%)	14 (70%)	14 (70%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
7 [0.986, 49.695]	0.051	13 [0.732, 230.775]	0.08

A contingency table for The first Headache with any severity - PT level in Region: Europe group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (29%)	10 (29%)
No	0 (0%)	24 (71%)	24 (71%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.62	0.82

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Lead-in Bleed count Category: >=1 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (28%)	11 (28%)
No	0 (0%)	29 (72%)	29 (72%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

A contingency table for The first Headache with any severity - PT level in Lead-in Bleed count Category: 0 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	5 (36%)	5 (36%)
No	0 (0%)	9 (64%)	9 (64%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
6 [0.845, 42.596]	0.073	11 [0.608, 198.941]	0.104

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
2.09	0.762

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (27%)	12 (27%)
No	0 (0%)	32 (73%)	32 (73%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Headache with any severity - PT level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (40%)	4 (40%)
No	0 (0%)	6 (60%)	6 (60%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
2.78	0.679

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Headache with any severity - PT level in Baseline Nab Titer category: Negative group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (36%)	12 (36%)
No	0 (0%)	21 (64%)	21 (64%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first Headache with any severity - PT level in Baseline Nab Titer category: Positive group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (19%)	4 (19%)
No	0 (0%)	17 (81%)	17 (81%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
2.78	0.54

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

12. UE unabhängig vom Schweregrad (Alanin-Aminotransferase erhöht) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first Alanine Aminotransferase Increased with any severity - PT level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (23%)	10 (23%)
No	0 (0%)	34 (77%)	34 (77%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first Alanine Aminotransferase Increased with any severity - PT level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	1 (10%)	1 (10%)
No	0 (0%)	9 (90%)	9 (90%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2 [0.282, 14.199]	0.498	3 [0.122, 73.647]	0.511

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
7	0.298

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first Alanine Aminotransferase Increased with any severity - PT level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (23%)	10 (23%)
No	0 (0%)	34 (77%)	34 (77%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first Alanine Aminotransferase Increased with any severity - PT level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	1 (10%)	1 (10%)
No	0 (0%)	9 (90%)	9 (90%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2 [0.282, 14.199]	0.498	3 [0.122, 73.647]	0.511

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
7	0.298

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

13. UE nach Schweregrad (Zeit bis zum ersten UE; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first mild AE of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	26 (65%)	2.1 (1.4, 3.4)	5.5 (3.0, —)	9.2 (6.2, —)
Post-Treament Month 0 - 24	40	40 (100%)	0.05 (0.03, 0.07)	0.15 (0.07, 0.26)	0.38 (0.23, 1.6)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild AE of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	11 (79%)	2.0 (0.26, 3.4)	4.1 (0.59, —)	9.0 (3.4, —)
Post-Treament Month 0 - 24	14	14 (100%)	0.03 (0.03, 0.03)	0.05 (0.03, 0.10)	0.10 (0.03, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
39 [5.36, 283.86]	0

HR [95% CI] of Race: Non-white or not specified group	p.value
13 [1.7, 99.37]	0.013

Interaction as a ratio of HRs [95% CI]	p.value
0.33 [0.02, 5.72]	0.449

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a

		The first mild AE of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**

subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild AE of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	10 (50%)	3.9 (0.07, 5.5)	9.0 (3.0, —)	9.0 (—, —)
Post-Treament Month 0 - 24	20	20 (100%)	0.05 (0.03, 0.13)	0.16 (0.03, 0.39)	0.56 (0.16, 5.7)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild AE of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	27 (79%)	1.7 (0.59, 2.8)	3.4 (2.0, 5.9)	7.3 (5.6, —)
Post-Treament Month 0 - 24	34	34 (100%)	0.03 (0.03, 0.07)	0.07 (0.03, 0.26)	0.33 (0.10, 1.6)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
19 [2.54, 141.93]	0.004

HR [95% CI] of Region: Europe group	p.value
33 [4.51, 241.28]	0.001

Interaction as a ratio of HRs [95% CI]	p.value
0.58 [0.03, 9.74]	0.702

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild AE of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	30 (75%)	2.0 (0.72, 2.9)	3.5 (2.5, 6.0)	9.0 (5.8, —)
Post-Treament Month 0 - 24	40	40 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.26)	1.2 (0.16, 2.5)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild AE of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	7 (50%)	5.4 (0.43, 5.9)	7.0 (1.9, —)	— (5.9, —)
Post-Treament Month 0 - 24	14	14 (100%)	0.03 (0.03, 0.10)	0.10 (0.03, 0.23)	0.23 (0.10, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
19 [4.58, 78.76]	0

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474783.32 [0, Inf]	0.998

Interaction as a ratio of HRs [95% CI]	p.value
85024988.6 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first mild AE of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	29 (66%)	2.3 (1.4, 3.4)	5.5 (3.0, 7.3)	9.2 (6.2, —)
Post-Treament Month 0 - 24	44	44 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.23)	0.38 (0.16, 1.9)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild AE of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	8 (80%)	1.2 (0.43, 4.7)	3.4 (0.43, —)	9.0 (2.0, —)
Post-Treament Month 0 - 24	10	10 (100%)	0.03 (0.03, 0.10)	0.08 (0.03, 0.33)	0.33 (0.07, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
21.5 [2.9, 159.67]	0.003

HR [95% CI] of Status of target joint at screening: Presence group	p.value
1615474790.45 [391355493.53, 6668511983.97]	0

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, 0]	0

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first mild AE of Baseline Nab Titer category: Negative group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	21 (64%)	3.2 (0.46, 5.4)	5.8 (4.7, —)	9.2 (6.2, —)
Post-Treament Month 0 - 24	33	33 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.26)	0.33 (0.20, 2.5)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild AE of Baseline Nab Titer category: Positive group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	16 (76%)	1.8 (0.43, 2.1)	2.9 (1.8, 7.3)	7.3 (3.0, —)
Post-Treament Month 0 - 24	21	21 (100%)	0.03 (0.03, 0.07)	0.07 (0.03, 0.23)	0.39 (0.10, 2.8)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
32 [4.37, 234.18]	0.001

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
20 [2.68, 149.02]	0.003

Interaction as a ratio of HRs [95% CI]	p.value
1.6 [0.09, 27.05]	0.745

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild AE of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	13 (62%)	3.0 (1.4, 4.9)	5.9 (3.0, —)	9.2 (6.0, —)
Post-Treament Month 0 - 24	21	21 (100%)	0.03 (0.03, 0.07)	0.10 (0.03, 0.16)	0.23 (0.10, 5.7)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild AE of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	24 (73%)	1.9 (0.43, 2.5)	3.7 (2.1, 6.2)	9.0 (5.6, —)
Post-Treament Month 0 - 24	33	33 (100%)	0.03 (0.03, 0.07)	0.10 (0.07, 0.33)	1.1 (0.26, 2.5)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
1615474785.02 [0, Inf]	0.998

HR [95% CI] of Hepatitis B or C: Yes group	p.value
16 [3.83, 66.76]	0

Interaction as a ratio of HRs [95% CI]	p.value
100967174.06 [0, Inf]	0.998

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild AE of Baseline Steatosis grade Category: <S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	19 (68%)	1.8 (0.43, 4.7)	5.5 (2.2, 7.3)	— (5.9, —)
Post-Treament Month 0 - 24	28	28 (100%)	0.03 (0.03, 0.07)	0.08 (0.03, 0.26)	0.34 (0.10, 4.3)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild AE of Baseline Steatosis grade Category: >=S2 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	8 (67%)	2.4 (0.26, 3.4)	4.4 (1.4, —)	— (3.4, —)
Post-Treament Month 0 - 24	12	12 (100%)	0.03 (0.03, 0.07)	0.11 (0.03, 0.39)	0.34 (0.07, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
13 [3.09, 54.77]	0

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
1615474783.83 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
124267291.06 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

14. UE nach Schweregrad (Erstes Ereignis Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	6 (15%)	— (6.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	22 (55%)	2.2 (0.46, 5.6)	13 (3.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Race: Non-white or not specified group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	2 (14%)	— (0.43, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	4 (29%)	14 (0.03, —)	— (1.1, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
4.25 [1.43, 12.63]	0.009

HR [95% CI] of Race: Non-white or not specified group	p.value
3 [0.31, 28.84]	0.341

Interaction as a ratio of HRs [95% CI]	p.value
0.71 [0.06, 8.7]	0.786

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

Characteristic	N	n (%)	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Race: White group - Time unit: Months 25% Perc (95% CI)	50% Perc (95% CI)	75% Perc (95% CI)
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Region: USA group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	2 (10%)	— (3.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	7 (35%)	2.7 (0.03, —)	— (1.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Region: Europe group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	6 (18%)	— (5.6, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	19 (56%)	2.2 (0.46, 6.4)	16 (3.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
7 [0.86, 56.89]	0.069

HR [95% CI] of Region: Europe group	p.value
3.25 [1.06, 9.97]	0.039

Interaction as a ratio of HRs [95% CI]	p.value
2.15 [0.2, 23.18]	0.527

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	6 (15%)	— (6.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	20 (50%)	1.4 (0.30, 5.6)	28 (3.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	2 (14%)	— (0.43, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	6 (43%)	6.1 (1.2, —)	— (2.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
5 [1.45, 17.27]	0.011

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
2.5 [0.49, 12.89]	0.273

Interaction as a ratio of HRs [95% CI]	p.value
0.5 [0.06, 3.91]	0.509

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	5 (11%)	— (7.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	21 (48%)	3.2 (0.82, 6.4)	— (5.6, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	3 (30%)	5.7 (0.43, —)	— (0.43, —)	— (—, —)
Post-Treament Month 0 - 24	10	5 (50%)	0.46 (0.10, —)	19 (0.10, —)	— (6.5, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
4 [1.34, 11.96]	0.013

HR [95% CI] of Status of target joint at screening: Presence group	p.value
4 [0.45, 35.79]	0.215

Interaction as a ratio of HRs [95% CI]	p.value
1 [0.09, 11.59]	1

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	4 (12%)	— (6.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	15 (45%)	4.3 (0.30, 6.5)	— (6.1, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	4 (19%)	— (0.43, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	11 (52%)	1.1 (0.03, 2.2)	14 (1.1, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
3.67 [1.02, 13.14]	0.046

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
4.5 [0.97, 20.83]	0.054

Interaction as a ratio of HRs [95% CI]	p.value
0.81 [0.11, 5.99]	0.84

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	3 (14%)	— (2.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	9 (43%)	1.1 (0.03, 5.6)	— (1.1, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	5 (15%)	— (5.6, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	17 (52%)	3.7 (0.82, 6.5)	23 (6.1, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
4 [0.85, 18.84]	0.08

HR [95% CI] of Hepatitis B or C: Yes group	p.value
4 [1.13, 14.17]	0.032

Interaction as a ratio of HRs [95% CI]	p.value
1 [0.14, 7.39]	1

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	5 (18%)	— (1.1, —)	— (7.3, —)	— (—, —)
Post-Treament Month 0 - 24	28	16 (57%)	2.0 (0.46, 4.3)	10 (2.7, —)	— (23, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild Musculoskeletal and Connective Tissue Disorders - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	1 (8.3%)	— (3.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	12	3 (25%)	16 (0.03, —)	— (0.30, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
4.67 [1.34, 16.24]	0.015

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
3 [0.31, 28.84]	0.341

Interaction as a ratio of HRs [95% CI]	p.value
0.64 [0.05, 8.52]	0.738

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

15. UE nach Schweregrad (Erstes Ereignis Erkrankungen des Gastrointestinaltrakts; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

	The first mild Gastrointestinal Disorders - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	4 (10%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	17 (42%)	3.4 (0.16, 9.3)	— (5.7, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild Gastrointestinal Disorders - SOC level of Race: Non-white or not specified group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	2 (14%)	— (2.9, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	5 (36%)	12 (0.03, —)	— (2.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
7.5 [1.72, 32.8]	0.007

HR [95% CI] of Race: Non-white or not specified group	p.value
1.5 [0.25, 8.98]	0.657

Interaction as a ratio of HRs [95% CI]	p.value
0.2 [0.02, 2.03]	0.174

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first mild Gastrointestinal Disorders - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first mild Gastrointestinal Disorders - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	10 (50%)	3.1 (0.13, 12)	26 (2.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Gastrointestinal Disorders - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	6 (18%)	— (4.9, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	12 (35%)	4.1 (0.07, —)	— (9.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1615474788.24 [0, Inf]	0.999

HR [95% CI] of Region: Europe group	p.value
2.5 [0.78, 7.97]	0.121

Interaction as a ratio of HRs [95% CI]	p.value
646189915.29 [0, Inf]	0.999

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Gastrointestinal Disorders - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	6 (15%)	— (5.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	16 (40%)	4.8 (0.16, 24)	— (12, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Gastrointestinal Disorders - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	6 (43%)	3.4 (0.03, —)	— (2.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
3 [0.97, 9.3]	0.057

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474789.88 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
538491596.63 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

	The first mild Gastrointestinal Disorders - SOC level of Status of target joint at screening: Absence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	5 (11%)	— (5.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	17 (39%)	3.7 (0.20, 24)	— (6.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

	The first mild Gastrointestinal Disorders - SOC level of Status of target joint at screening: Presence group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	1 (10%)	— (3.1, —)	— (3.1, —)	— (—, —)
Post-Treament Month 0 - 24	10	5 (50%)	0.36 (0.03, —)	23 (0.03, —)	— (18, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
3.75 [1.24, 11.3]	0.019

HR [95% CI] of Status of target joint at screening: Presence group	p.value
594299996.05 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Gastrointestinal Disorders - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	3 (9.1%)	— (5.8, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	11 (33%)	5.7 (0.20, —)	— (24, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Gastrointestinal Disorders - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	3 (14%)	— (2.9, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	11 (52%)	2.2 (0.03, 9.3)	18 (2.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
5 [1.1, 22.82]	0.038

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
4 [0.85, 18.84]	0.08

Interaction as a ratio of HRs [95% CI]	p.value
1.25 [0.14, 10.94]	0.84

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Gastrointestinal Disorders - SOC level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	3 (14%)	— (3.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	8 (38%)	3.5 (0.03, —)	— (3.5, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Gastrointestinal Disorders - SOC level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	3 (9.1%)	— (5.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	14 (42%)	3.9 (0.07, 12)	— (6.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
3.5 [0.73, 16.85]	0.118

HR [95% CI] of Hepatitis B or C: Yes group	p.value
5.5 [1.22, 24.81]	0.027

Interaction as a ratio of HRs [95% CI]	p.value
0.64 [0.07, 5.61]	0.684

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Gastrointestinal Disorders - SOC level of Baseline Steatosis grade Category: <S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	1 (3.6%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	28	11 (39%)	5.4 (0.03, —)	— (9.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Gastrointestinal Disorders - SOC level of Baseline Steatosis grade Category: >=S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	3 (25%)	8.0 (2.9, —)	— (3.1, —)	— (—, —)
Post-Treament Month 0 - 24	12	5 (42%)	1.5 (0.03, —)	— (0.16, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
8 [1, 63.96]	0.05

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
2.5 [0.49, 12.89]	0.273

Interaction as a ratio of HRs [95% CI]	p.value
0.31 [0.02, 4.41]	0.389

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

16. UE nach Schweregrad (Erstes Ereignis Erkrankungen der Atemwege, des Brustraums und Mediastinums; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	3 (7.5%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	11 (28%)	7.6 (1.2, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	3 (21%)	9.0 (0.26, —)	9.0 (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	14	7 (50%)	1.8 (0.07, 24)	27 (0.62, —)	— (24, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
5 [1.1, 22.82]	0.038

HR [95% CI] of Race: Non-white or not specified group	p.value
1.33 [0.3, 5.96]	0.706

Interaction as a ratio of HRs [95% CI]	p.value
0.27 [0.03, 2.25]	0.224

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a

	The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Race: White group - Time unit: Months				
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.					

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	3 (15%)	9.0 (2.0, —)	9.0 (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	20	4 (20%)	— (1.1, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	3 (8.8%)	— (6.2, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	14 (41%)	4.3 (0.46, 7.2)	— (4.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
1 [0.14, 7.1]	1

HR [95% CI] of Region: Europe group	p.value
4 [1.13, 14.17]	0.032

Interaction as a ratio of HRs [95% CI]	p.value
0.25 [0.02, 2.58]	0.244

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	5 (12%)	9.0 (6.2, —)	— (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	40	12 (30%)	8.0 (1.8, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	1 (7.1%)	— (5.5, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	6 (43%)	1.2 (0.59, —)	— (1.1, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
1.6 [0.52, 4.89]	0.41

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
1615474789.76 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
1009671743.6 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Status of target joint at screening: Absence group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	4 (9.1%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	14 (32%)	6.8 (1.1, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Status of target joint at screening: Presence group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	2 (20%)	9.0 (2.0, —)	9.0 (2.0, —)	9.0 (—, —)
Post-Treament Month 0 - 24	10	4 (40%)	4.3 (0.33, —)	— (0.33, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
3.33 [0.92, 12.11]	0.067

HR [95% CI] of Status of target joint at screening: Presence group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
1.67 [0.2, 14.05]	0.639

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	4 (12%)	— (5.5, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	12 (36%)	4.8 (1.1, —)	— (6.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	2 (9.5%)	9.0 (2.0, —)	— (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	21	6 (29%)	8.8 (0.07, —)	— (8.8, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
3.33 [0.92, 12.11]	0.067

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
2 [0.37, 10.92]	0.423

Interaction as a ratio of HRs [95% CI]	p.value
1.67 [0.2, 14.05]	0.639

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	1 (4.8%)	— (2.0, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	6 (29%)	24 (0.62, —)	— (24, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Respiratory, Thoracic and Mediastinal Disorders - SOC level of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	5 (15%)	9.0 (5.5, —)	9.0 (9.0, —)	— (9.0, —)
Post-Treament Month 0 - 24	33	12 (36%)	4.3 (0.33, —)	— (7.2, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
5 [0.58, 42.8]	0.142

HR [95% CI] of Hepatitis B or C: Yes group	p.value
2.25 [0.69, 7.31]	0.177

Interaction as a ratio of HRs [95% CI]	p.value
2.22 [0.19, 25.72]	0.523

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

17. UE nach Schweregrad (Untersuchungen; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first mild Investigations - SOC level in Race: White group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	15 (38%)	15 (38%)
No	0 (0%)	25 (62%)	25 (62%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
16 [2.254, 113.589]	0.006	31 [1.855, 518.116]	0.017

A contingency table for The first mild Investigations - SOC level in Race: Non-white or not specified group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (29%)	4 (29%)
No	0 (0%)	10 (71%)	10 (71%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
3.44	0.497

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (60%)	12 (60%)
No	0 (0%)	8 (40%)	8 (40%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first mild Investigations - SOC level in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (21%)	7 (21%)
No	0 (0%)	27 (79%)	27 (79%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
1.67	0.576

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Lead-in Bleed count Category: >=1 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (30%)	12 (30%)
No	0 (0%)	28 (70%)	28 (70%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first mild Investigations - SOC level in Lead-in Bleed count Category: 0 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (50%)	7 (50%)
No	0 (0%)	7 (50%)	7 (50%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
1.67	0.922

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	16 (36%)	16 (36%)
No	0 (0%)	28 (64%)	28 (64%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
17 [2.395, 120.689]	0.005	33 [1.98, 550.073]	0.015

A contingency table for The first mild Investigations - SOC level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	3 (30%)	3 (30%)
No	0 (0%)	7 (70%)	7 (70%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
4 [0.563, 28.397]	0.166	7 [0.362, 135.524]	0.199

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
4.71	0.407

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Baseline Nab Titer category: Negative group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (33%)	11 (33%)
No	0 (0%)	22 (67%)	22 (67%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

A contingency table for The first mild Investigations - SOC level in Baseline Nab Titer category: Positive group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	8 (38%)	8 (38%)
No	0 (0%)	13 (62%)	13 (62%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
9 [1.268, 63.894]	0.028	17 [0.981, 294.545]	0.051

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
1.35	0.91

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Hepatitis B or C: No group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (33%)	7 (33%)
No	0 (0%)	14 (67%)	14 (67%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

A contingency table for The first mild Investigations - SOC level in Hepatitis B or C: Yes group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (36%)	12 (36%)
No	0 (0%)	21 (64%)	21 (64%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (No vs. Yes)	p.value of the interaction test
0.6	0.788

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Race: White group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (35%)	14 (35%)
No	0 (0%)	26 (65%)	26 (65%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first mild Investigations - SOC level in Race: Non-white or not specified group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	4 (29%)	4 (29%)
No	0 (0%)	10 (71%)	10 (71%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
5 [0.704, 35.497]	0.107	9 [0.485, 167.171]	0.141

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
3.22	0.533

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Region: USA group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (55%)	11 (55%)
No	0 (0%)	9 (45%)	9 (45%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

A contingency table for The first mild Investigations - SOC level in Region: Europe group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (21%)	7 (21%)
No	0 (0%)	27 (79%)	27 (79%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
1.53	0.642

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Lead-in Bleed count Category: >=1 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (28%)	11 (28%)
No	0 (0%)	29 (72%)	29 (72%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

A contingency table for The first mild Investigations - SOC level in Lead-in Bleed count Category: 0 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (50%)	7 (50%)
No	0 (0%)	7 (50%)	7 (50%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
1.53	0.968

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	15 (34%)	15 (34%)
No	0 (0%)	29 (66%)	29 (66%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
16 [2.254, 113.589]	0.006	31 [1.855, 518.116]	0.017

A contingency table for The first mild Investigations - SOC level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	3 (30%)	3 (30%)
No	0 (0%)	7 (70%)	7 (70%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
4 [0.563, 28.397]	0.166	7 [0.362, 135.524]	0.199

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
4.43	0.438

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Baseline Nab Titer category: Negative group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (30%)	10 (30%)
No	0 (0%)	23 (70%)	23 (70%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first mild Investigations - SOC level in Baseline Nab Titer category: Positive group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	8 (38%)	8 (38%)
No	0 (0%)	13 (62%)	13 (62%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
9 [1.268, 63.894]	0.028	17 [0.981, 294.545]	0.051

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
1.24	0.962

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Investigations - SOC level in Hepatitis B or C: No group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	7 (33%)	7 (33%)
No	0 (0%)	14 (67%)	14 (67%)
Total	0 (0%)	21 (100%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
8 [1.127, 56.795]	0.037	15 [0.857, 262.648]	0.063

A contingency table for The first mild Investigations - SOC level in Hepatitis B or C: Yes group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	11 (33%)	11 (33%)
No	0 (0%)	22 (67%)	22 (67%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
12 [1.69, 85.192]	0.013	23 [1.355, 390.321]	0.03

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (No vs. Yes)	p.value of the interaction test
0.65	0.836

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

18. UE nach Schweregrad (Erkrankungen des Nervensystems; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first mild Nervous System Disorders - SOC level in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	3 (15%)	3 (15%)
No	0 (0%)	17 (85%)	17 (85%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
4 [0.563, 28.397]	0.166	7 [0.362, 135.524]	0.199

A contingency table for The first mild Nervous System Disorders - SOC level in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (29%)	10 (29%)
No	0 (0%)	24 (71%)	24 (71%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

This statistical output was generated with R version 4.2.1 (2022-06-23 ucrt)

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.33	0.534

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Nervous System Disorders - SOC level in Region: USA group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	3 (15%)	3 (15%)
No	0 (0%)	17 (85%)	17 (85%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
4 [0.563, 28.397]	0.166	7 [0.362, 135.524]	0.199

A contingency table for The first mild Nervous System Disorders - SOC level in Region: Europe group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (29%)	10 (29%)
No	0 (0%)	24 (71%)	24 (71%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.33	0.534

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

19. UE nach Schweregrad (Erstes Ereignis Arthralgie; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first mild Arthralgia - PT level of Race: White group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	3 (7.5%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	40	12 (30%)	4.9 (0.82, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Arthralgia - PT level of Race: Non-white or not specified group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	2 (14%)	— (1.1, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
5.5 [1.22, 24.81]	0.027

HR [95% CI] of Race: Non-white or not specified group	p.value
594299988.25 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
108054543.32 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Arthralgia - PT level of Lead-in Bleed count Category: >=1 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	2 (5.0%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	40	12 (30%)	6.5 (0.82, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Arthralgia - PT level of Lead-in Bleed count Category: 0 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	1 (7.1%)	— (5.6, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	2 (14%)	— (1.2, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
10 [1.28, 78.12]	0.028

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
2 [0.18, 22.06]	0.571

Interaction as a ratio of HRs [95% CI]	p.value
0.2 [0.01, 4.72]	0.318

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first mild Arthralgia - PT level of Status of target joint at screening: Absence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	2 (4.5%)	— (8.6, —)	— (8.6, —)	— (—, —)
Post-Treament Month 0 - 24	44	12 (27%)	6.5 (1.1, —)	— (—, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first mild Arthralgia - PT level of Status of target joint at screening: Presence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	1 (10%)	— (1.1, —)	— (1.1, —)	— (—, —)
Post-Treament Month 0 - 24	10	2 (20%)	— (0.46, —)	— (0.46, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
5.5 [1.22, 24.81]	0.027

HR [95% CI] of Status of target joint at screening: Presence group	p.value
594300002.71 [0, Inf]	0.999

Interaction as a ratio of HRs [95% CI]	p.value
0 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

20. UE nach Schweregrad (Ermüdung; mild) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first mild Fatigue - PT level in Race: White group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (35%)	14 (35%)
No	0 (0%)	26 (65%)	26 (65%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first mild Fatigue - PT level in Race: Non-white or not specified group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	0 (0%)	0 (0%)
No	0 (0%)	14 (100%)	14 (100%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1 [0.141, 7.099]	1	1 [0.02, 50.4]	1

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
29	0.039

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Fatigue - PT level in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (10%)	2 (10%)
No	0 (0%)	18 (90%)	18 (90%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

A contingency table for The first mild Fatigue - PT level in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (35%)	12 (35%)
No	0 (0%)	22 (65%)	22 (65%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.2	0.334

This statistical output was generated with R version 4.2.1 (2022-06-23 ucrt)

Ratio of ORs (USA vs. Europe)	p.value of the interaction test

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Fatigue - PT level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (27%)	12 (27%)
No	0 (0%)	32 (73%)	32 (73%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first mild Fatigue - PT level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (20%)	2 (20%)
No	0 (0%)	8 (80%)	8 (80%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5	0.397

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Fatigue - PT level in Race: White group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	14 (35%)	14 (35%)
No	0 (0%)	26 (65%)	26 (65%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
15 [2.113, 106.49]	0.007	29 [1.73, 486.161]	0.019

A contingency table for The first mild Fatigue - PT level in Race: Non-white or not specified group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	0 (0%)	0 (0%)
No	0 (0%)	14 (100%)	14 (100%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1 [0.141, 7.099]	1	1 [0.02, 50.4]	1

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
29	0.039

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Fatigue - PT level in Region: USA group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (10%)	2 (10%)
No	0 (0%)	18 (90%)	18 (90%)
Total	0 (0%)	20 (100%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

A contingency table for The first mild Fatigue - PT level in Region: Europe group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (35%)	12 (35%)
No	0 (0%)	22 (65%)	22 (65%)
Total	0 (0%)	34 (100%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.2	0.334

This statistical output was generated with R version 4.2.1 (2022-06-23 ucrt)

Ratio of ORs (USA vs. Europe)	p.value of the interaction test

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first mild Fatigue - PT level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	12 (27%)	12 (27%)
No	0 (0%)	32 (73%)	32 (73%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
13 [1.831, 92.291]	0.01	25 [1.48, 422.263]	0.025

A contingency table for The first mild Fatigue - PT level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (20%)	2 (20%)
No	0 (0%)	8 (80%)	8 (80%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5	0.397

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

21. UE nach Schweregrad (Zeit bis zum ersten UE; moderat) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first moderate AE of Race: White group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	5 (12%)	— (4.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	27 (68%)	1.1 (0.26, 4.0)	10 (2.1, 20)	— (17, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Race: Non-white or not specified group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	4 (29%)	5.0 (0.49, —)	— (3.1, —)	— (—, —)
Post-Treament Month 0 - 24	14	10 (71%)	1.3 (0.03, 7.5)	7.6 (0.99, —)	— (7.5, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Race: White group	p.value
18 [2.4, 134.83]	0.005

HR [95% CI] of Race: Non-white or not specified group	p.value
2 [0.5, 8]	0.327

Interaction as a ratio of HRs [95% CI]	p.value
0.11 [0.01, 1.28]	0.078

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first moderate AE of Region: USA group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	20	3 (15%)	— (3.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	20	17 (85%)	0.49 (0.03, 0.99)	3.2 (0.26, 17)	17 (4.8, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Region: Europe group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	34	6 (18%)	— (1.3, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	34	20 (59%)	2.1 (0.53, 6.1)	13 (2.9, —)	— (20, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Region: USA group	p.value
11 [1.42, 85.2]	0.022

HR [95% CI] of Region: Europe group	p.value
4.33 [1.23, 15.21]	0.022

Interaction as a ratio of HRs [95% CI]	p.value
2.54 [0.23, 28.02]	0.447

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first moderate AE of Lead-in Bleed count Category: >=1 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	40	8 (20%)	— (3.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	40	29 (72%)	1.1 (0.26, 2.1)	6.5 (1.5, 18)	— (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Lead-in Bleed count Category: 0 group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	14	1 (7.1%)	— (1.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	14	8 (57%)	4.8 (0.03, 11)	12 (0.72, —)	— (11, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Lead-in Bleed count Category: >=1 group	p.value
6.33 [1.87, 21.4]	0.003

HR [95% CI] of Lead-in Bleed count Category: 0 group	p.value
5 [0.58, 42.8]	0.142

Interaction as a ratio of HRs [95% CI]	p.value
0.79 [0.07, 9.32]	0.851

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first moderate AE of Status of target joint at screening: Absence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	6 (14%)	— (3.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	44	28 (64%)	0.89 (0.10, 2.6)	10 (1.9, —)	— (20, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Status of target joint at screening: Presence group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	3 (30%)	5.0 (1.4, —)	— (1.4, —)	— (—, —)
Post-Treament Month 0 - 24	10	9 (90%)	1.5 (0.26, 7.7)	6.6 (0.26, 17)	17 (5.5, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
9.5 [2.21, 40.78]	0.002

HR [95% CI] of Status of target joint at screening: Presence group	p.value
2.5 [0.49, 12.89]	0.273

Interaction as a ratio of HRs [95% CI]	p.value
3.8 [0.42, 34.08]	0.233

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first moderate AE of Baseline Nab Titer category: Negative group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	3 (9.1%)	— (4.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	23 (70%)	1.3 (0.03, 2.6)	6.1 (1.5, 18)	— (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Baseline Nab Titer category: Positive group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	6 (29%)	5.0 (0.49, —)	— (5.0, —)	— (—, —)
Post-Treament Month 0 - 24	21	14 (67%)	1.5 (0.03, 7.5)	9.7 (1.5, —)	— (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Nab Titer category: Negative group	p.value
1615474785.36 [0, Inf]	0.998

HR [95% CI] of Baseline Nab Titer category: Positive group	p.value
1.75 [0.51, 5.98]	0.372

Interaction as a ratio of HRs [95% CI]	p.value
923128448.78 [0, Inf]	0.998

The model did not converge. The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first moderate AE of Hepatitis B or C: No group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	1 (4.8%)	— (3.1, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	17 (81%)	0.99 (0.03, 2.9)	9.7 (0.99, 18)	20 (15, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Hepatitis B or C: Yes group - Time unit: Months			
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	8 (24%)	— (1.2, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	33	20 (61%)	1.3 (0.20, 4.0)	7.7 (1.9, —)	— (18, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
10 [1.28, 78.12]	0.028

HR [95% CI] of Hepatitis B or C: Yes group	p.value
4.67 [1.34, 16.24]	0.015

Interaction as a ratio of HRs [95% CI]	p.value
2.14 [0.19, 23.72]	0.534

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first moderate AE of Baseline Steatosis grade Category: <S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	28	4 (14%)	— (1.4, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	28	16 (57%)	3.8 (0.20, 11)	17 (6.1, —)	— (20, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first moderate AE of Baseline Steatosis grade Category: >=S2 group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	12	1 (8.3%)	— (0.49, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	12	9 (75%)	1.3 (0.03, 2.9)	6.3 (0.03, —)	25 (2.9, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Baseline Steatosis grade Category: <S2 group	p.value
9 [1.14, 71.04]	0.037

HR [95% CI] of Baseline Steatosis grade Category: >=S2 group	p.value
6 [0.72, 49.84]	0.097

Interaction as a ratio of HRs [95% CI]	p.value
0.67 [0.03, 12.84]	0.788

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

22. UE nach Schweregrad (Erkrankungen des Nervensystems; moderat) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for The first moderate Nervous System Disorders - SOC level in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (23%)	10 (23%)
No	0 (0%)	34 (77%)	34 (77%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first moderate Nervous System Disorders - SOC level in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	1 (10%)	1 (10%)
No	0 (0%)	9 (90%)	9 (90%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2 [0.282, 14.199]	0.498	3 [0.122, 73.647]	0.511

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
7	0.298

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for The first moderate Nervous System Disorders - SOC level in Status of target joint at screening: Absence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (23%)	10 (23%)
No	0 (0%)	34 (77%)	34 (77%)
Total	0 (0%)	44 (100%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for The first moderate Nervous System Disorders - SOC level in Status of target joint at screening: Presence group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	1 (10%)	1 (10%)
No	0 (0%)	9 (90%)	9 (90%)
Total	0 (0%)	10 (100%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2 [0.282, 14.199]	0.498	3 [0.122, 73.647]	0.511

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
7	0.298

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

23. SUE (Zeit bis zum ersten SUE) – Subgruppenanalysen – Studie HOPE-B – Monat 24

		The first serious AE of Status of target joint at screening: Absence group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	44	3 (6.8%)	— (7.9, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	44	10 (23%)	33 (6.1, —)	33 (—, —)	33 (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first serious AE of Status of target joint at screening: Presence group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	10	1 (10%)	— (0.43, —)	— (0.43, —)	— (—, —)
Post-Treament Month 0 - 24	10	4 (40%)	12 (1.3, —)	— (1.3, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Status of target joint at screening: Absence group	p.value
2 [0.5, 8]	0.327

HR [95% CI] of Status of target joint at screening: Presence group	p.value
1 [0.06, 15.99]	1

Interaction as a ratio of HRs [95% CI]	p.value
2 [0.09, 44.35]	0.661

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

		The first serious AE of Hepatitis B or C: No group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	21	0 (0%)	— (—, —)	— (—, —)	— (—, —)
Post-Treament Month 0 - 24	21	4 (19%)	33 (0.07, —)	33 (—, —)	33 (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

		The first serious AE of Hepatitis B or C: Yes group - Time unit: Months		
Characteristic	**N**	**n (%)**	**25% Perc (95% CI)**	**50% Perc (95% CI)**	**75% Perc (95% CI)**
Treatment Period					
Lead-in	33	4 (12%)	— (5.1, —)	— (7.9, —)	— (—, —)
Post-Treament Month 0 - 24	33	10 (30%)	24 (6.1, —)	— (24, —)	— (—, —)

25% Perc: 25% Percentile 50% Perc: 50% Percentile 75% Perc: 75% Percentile HR: Hazard Ratio CI: Confidence Interval; Confidence intervals of time to events are computed based on the complementary log-log transformation.
The distribution of time to events was estimated by Kaplan-Meier method.

HR [95% CI] of Hepatitis B or C: No group	p.value
1615474795.86 [0, Inf]	0.999

HR [95% CI] of Hepatitis B or C: Yes group	p.value
1 [0.25, 4]	1

Interaction as a ratio of HRs [95% CI]	p.value
1615474795.86 [0, Inf]	0.999

The stratified Cox model was used to address a paired design of the study and estimate the hazard ratio and its two-sided 95% CI. The treatment period, a subgroup variable, and the interaction term between the treatment period and a subgroup variable was the explanatory variable and subject ID was a strata variable.

24. Gesamtrate an Patienten mit ≥1 AESI – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for AESI in Lead-in Bleed count Category: >=1 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (25%)	10 (25%)
No	0 (0%)	30 (75%)	30 (75%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for AESI in Lead-in Bleed count Category: 0 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (14%)	2 (14%)
No	0 (0%)	12 (86%)	12 (86%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
4.2	0.442

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	Lead-in		
	Yes	No	Total

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for AESI in Lead-in Bleed count Category: >=1 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	10 (25%)	10 (25%)
No	0 (0%)	30 (75%)	30 (75%)
Total	0 (0%)	40 (100%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
11 [1.549, 78.093]	0.016	21 [1.231, 358.386]	0.035

A contingency table for AESI in Lead-in Bleed count Category: 0 group - month 18 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	2 (14%)	2 (14%)
No	0 (0%)	12 (86%)	12 (86%)
Total	0 (0%)	14 (100%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3 [0.423, 21.298]	0.275	5 [0.24, 104.153]	0.303

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
4.2	0.442

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

25. Anti-AAV5 NAb (Titer) (LOD = 7) – Subgruppenanalysen – Studie HOPE-B – Monat 24

A contingency table for Nab titer Positive in Race: White group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	12 (30%)	28 (70%)	40 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	12 (30%)	28 (70%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3.154 [1.997, 4.982]	<0.001	57 [3.48, 933.666]	0.005

A contingency table for Nab titer Positive in Race: Non-white or not specified group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	9 (64%)	5 (36%)	14 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	9 (64%)	5 (36%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1.5 [1.014, 2.22]	0.042	11 [0.608, 198.941]	0.104

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (White vs. Non-white or not specified)	p.value of the interaction test
5.18	0.22

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for Nab titer Positive in Region: USA group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	9 (45%)	11 (55%)	20 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	9 (45%)	11 (55%)	20 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2.1 [1.314, 3.355]	0.002	23 [1.355, 390.321]	0.03

A contingency table for Nab titer Positive in Region: Europe group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	12 (35%)	22 (65%)	34 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	12 (35%)	22 (65%)	34 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2.692 [1.733, 4.183]	<0.001	45 [2.73, 741.852]	0.008

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (USA vs. Europe)	p.value of the interaction test
0.51	0.658

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Ratio of ORs (USA vs. Europe)	p.value of the interaction test

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for Nab titer Positive in Lead-in Bleed count Category: >=1 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	18 (45%)	22 (55%)	40 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	18 (45%)	22 (55%)	40 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2.158 [1.541, 3.022]	<0.001	45 [2.73, 741.852]	0.008

A contingency table for Nab titer Positive in Lead-in Bleed count Category: 0 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	3 (21%)	11 (79%)	14 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	3 (21%)	11 (79%)	14 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3.75 [1.561, 9.01]	0.003	23 [1.355, 390.321]	0.03

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (>=1 vs. 0)	p.value of the interaction test
1.96	0.987

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for Nab titer Positive in Status of target joint at screening: Absence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	16 (36%)	28 (64%)	44 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	16 (36%)	28 (64%)	44 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2.647 [1.807, 3.877]	<0.001	57 [3.48, 933.666]	0.005

A contingency table for Nab titer Positive in Status of target joint at screening: Presence group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	5 (50%)	5 (50%)	10 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	5 (50%)	5 (50%)	10 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1.833 [1.015, 3.31]	0.044	11 [0.608, 198.941]	0.104

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Absence vs. Presence)	p.value of the interaction test
5.18	0.313

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for Nab titer Positive in Baseline Nab Titer category: Negative group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	0 (0%)	33 (100%)	33 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	0 (0%)	33 (100%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
34 [4.789, 241.377]	<0.001	67 [4.105, 1093.523]	0.003

A contingency table for Nab titer Positive in Baseline Nab Titer category: Positive group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	21 (100%)	0 (0%)	21 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	21 (100%)	0 (0%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
1 [0.915, 1.093]	1	1 [0.02, 50.4]	1

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (Negative vs. Positive)	p.value of the interaction test
67	0

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for Nab titer Positive in Hepatitis B or C: No group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	5 (24%)	16 (76%)	21 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	5 (24%)	16 (76%)	21 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
3.667 [1.815, 7.409]	<0.001	33 [1.98, 550.073]	0.015

A contingency table for Nab titer Positive in Hepatitis B or C: Yes group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	16 (48%)	17 (52%)	33 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	16 (48%)	17 (52%)	33 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2 [1.415, 2.826]	<0.001	35 [2.105, 582.032]	0.013

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (No vs. Yes)	p.value of the interaction test
0.94	0.774

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Ratio of ORs (No vs. Yes)	p.value of the interaction test

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design

A contingency table for Nab titer Positive in Baseline Steatosis grade Category: <S2 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	10 (36%)	18 (64%)	28 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	10 (36%)	18 (64%)	28 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2.636 [1.634, 4.253]	<0.001	37 [2.23, 613.993]	0.012

A contingency table for Nab titer Positive in Baseline Steatosis grade Category: >=S2 group - month 24 cut-off; n (cell%)

	Lead-in		
	Yes	No	Total
Post-treatment			
Yes	5 (42%)	7 (58%)	12 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Total	5 (42%)	7 (58%)	12 (100%)

RR [95% CI]	RR: p-value	OR [95% CI]	OR: p-value
2.167 [1.157, 4.059]	0.016	15 [0.857, 262.648]	0.063

Mantel-Haenszel risk ratios and Mantel-Haenszel odds ratios were used to address a paired design and estimate the effect measures and their 95% CI. P-values of the risk ratios and odds ratios were calculated from 95% CI as in the overall analysis.

Ratio of ORs (<S2 vs. >=S2)	p.value of the interaction test
2.47	0.606

Interaction was assessed by the Breslow-Day test. The Breslow-Day test examines whether the odds ratios are the same for the subgroups. The subgroup tables were not stratified by subjects so the test was naively conducted without accounting for a paired design