

Anhang 4-G: Ergänzende Daten**Inhaltsverzeichnis**

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Anhang 4-G1: Ergänzende Daten zur Studie BASIS

Anhang 4-G1.1: Disposition und Baseline-Charakteristika

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Disposition Events Summary
 All Safety Set

	Routine Prophylaxis During OP (N=72) n (%)
Disposition phase: Observational Phase (OP)	
Participants Entered	72 (100.0%)
Discontinued	6 (8.3%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Protocol Deviation	1 (1.4%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	0 (0.0%)
Medication Error Without Associated Adverse Event	0 (0.0%)
No Longer Meets Eligibility Criteria	5 (6.9%)
Withdrawal By Parent/Guardian	0 (0.0%)
Global Deterioration Of Health Status	0 (0.0%)
Other	0 (0.0%)
Completed	66 (91.7%)
Completed but not Entered ATP	1 (1.4%)
Disposition phase: Active Treatment Phase (ATP)	
Participants Entered	65 (90.3%)
Discontinued	5 (6.9%)
Adverse Event	1 (1.4%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Protocol Deviation	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	4 (5.6%)
Medication Error Without Associated Adverse Event	0 (0.0%)
No Longer Meets Eligibility Criteria	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Failure to Meet Randomization Criteria	0 (0.0%)
Global Deterioration Of Health Status	0 (0.0%)
Other	0 (0.0%)
Completed	60 (83.3%)
Disposition Phase: Follow-up	
Participants Entered	7 (9.7%)
Discontinued	0 (0.0%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Protocol Deviation	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	0 (0.0%)
Medication Error Without Associated Adverse Event	0 (0.0%)
No Longer Meets Eligibility Criteria	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Failure to Meet Randomization Criteria	0 (0.0%)
Global Deterioration Of Health Status	0 (0.0%)
Other	0 (0.0%)
Completed	7 (9.7%)

N: Number of patients; n: Number of patients with non-missing status; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Baseline and Demographic Characteristics
 All Safety Set

	Routine Prophylaxis During OP (N=72)	
Age (Years)		
Mean (SD)	32.44	(14.17)
Median	31.00	
Min, Max	13.00,	61.00
Q1, Q3	19.00,	44.50
n (missing)	72	(0)
Age (Years), n(%)		
<18	13	(18.1%)
18-44	41	(56.9%)
45-64	18	(25.0%)
65-74	0	(0.0%)
>=75	0	(0.0%)
Sex, n(%)		
Male	72	(100.0%)
Race, n(%)		
Black or African American	0	(0.0%)
American Indian or Alaska Native	0	(0.0%)
Asian	31	(43.1%)
Native Hawaiian or Other Pacific Islander	0	(0.0%)
White	41	(56.9%)
Not Reported	0	(0.0%)
Ethnicity, n(%)		
Hispanic or Latino	9	(12.5%)
Not Hispanic or Latino	63	(87.5%)
Baseline eGFR* (mL/min/1.73m^2), n(%)		
missing	3	(4.2%)
>=90	53	(73.6%)
>= 60 to < 90	15	(20.8%)
>= 30 to < 60	1	(1.4%)
<30	0	(0.0%)
Weight (kg)		
Mean (SD)	70.79	(15.79)
Median	71.65	
Min, Max	35.00,	120.00
Q1, Q3	61.90,	80.70
n (missing)	72	(0)
Height (cm)		
Mean (SD)	170.53	(8.99)
Median	170.30	
Min, Max	141.00,	185.00
Q1, Q3	166.45,	178.00
n (missing)	72	(0)
Body Mass Index (kg/m^2)		
Mean (SD)	24.15	(4.23)
Median	24.12	
Min, Max	16.61,	35.95
Q1, Q3	21.49,	27.29
n (missing)	72	(0)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Baseline and Demographic Characteristics
 All Safety Set

	Routine Prophylaxis During OP (N=72)
Hemophilia Type, n(%)	
Hemophilia A	72 (100.0%)
Hemophilia B	0 (0.0%)
Age Groups, n(%)	
Adolescents (Ages 12 to < 18)	13 (18.1%)
Adults (Ages 18 to < 75)	59 (81.9%)
Age and Hemophilia Type, n(%)	
Adolescents Hem A	13 (18.1%)
Adolescents Hem B	0 (0.0%)
Adults Hem A	59 (81.9%)
Adults Hem B	0 (0.0%)
Factor VIII Inhibitor at Baseline, n(%)	
Positive	0 (0.0%)
Negative	72 (100.0%)
ISTH Disease Severity, n(%)	
Mild	0 (0.0%)
Moderate	0 (0.0%)
Severe	72 (100.0%)
Geographical Region, n(%)	
Asia	25 (34.7%)
Europe	27 (37.5%)
Middle East	10 (13.9%)
North America	10 (13.9%)
Number of Target Joints at Baseline, n(%)	
0	29 (40.3%)
1	18 (25.0%)
2	13 (18.1%)
>=3	12 (16.7%)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Treatment duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	176.75 (25.852)	191.97 (11.928)
	Median	183.00	191.00
	Q1, Q3	183.00, 183.00	185.00, 197.00
	Min, Max	28.0, 183.0	173.0, 252.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	344.71 (69.586)	191.97 (11.928)
	Median	364.00	191.00
	Q1, Q3	361.00, 364.00	185.00, 197.00
	Min, Max	28.0, 378.0	173.0, 252.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as the last dose date - the first dose date + 7.
For 6-month ATP: min(the last dose date - the first dose date + 7, 183)

Anhang 4-G1.2: Blutungsereignisse

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for total bleeds (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for total bleeds
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for total bleeds
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	17 (26.2)	21 (32.3)
	Number of bleeds		
	Number	329	329
	Mean (SD)	5.06 (7.616)	5.06 (7.239)
	Median	2.0	2.0
	Q1, Q3	0.0 6.0	0.0 6.0
	Min, Max	0 37	0 29
	Annualized bleeding rate (ABR)		
	Mean (SD)	6.28 (9.321)	10.26 (14.821)
	Median	2.03	3.89
	Q1, Q3	0.00 6.10	0.00 12.59
	Min, Max	0.00 37.54	0.00 59.51
	Model derived ABR [1]		
	Estimate (95% CI)	6.19 (4.28, 8.95)	10.25 (7.11, 14.79)
	Rate Ratio [1]		
	Estimate (95% CI)	0.60 (0.36, 1.02)	
	p-value	0.0570	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	6.19 (3.98, 8.41)	10.23 (6.66, 13.80)
	Treatment difference [2]		
	Estimate (95% CI)	-4.04 (-7.39, -0.68)	
	p-value	0.0184	
	Percentage reduction [3]		
	Estimate (95% CI)	39.45 (10.96, 58.83)	
	p-value	0.0108	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for total bleeds – Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							0.6707
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	1.97 (0.59, 6.60)	7/ 13 (53.8)	4.18 (1.26, 13.87)	0.47 (0.09, 2.59)	0.3860	
	Adults (Ages 18 to < 75)	8/ 52 (15.4)	7.26 (5.00, 10.55)	14/ 52 (26.9)	11.77 (8.13, 17.04)	0.62 (0.36, 1.04)	0.0715	
	Region							0.8183
	Asia	4/ 25 (16.0)	10.09 (6.07, 16.78)	6/ 25 (24.0)	15.27 (9.21, 25.34)	0.66 (0.32, 1.35)	0.2578	
	Europe	7/ 20 (35.0)	4.60 (2.33, 9.09)	7/ 20 (35.0)	7.56 (3.86, 14.79)	0.61 (0.23, 1.58)	0.3091	
	Middle East	3/ 10 (30.0)	3.99 (1.49, 10.68)	3/ 10 (30.0)	11.05 (4.31, 28.29)	0.36 (0.09, 1.41)	0.1426	
	North America	3/ 10 (30.0)	1.93 (0.91, 4.07)	5/ 10 (50.0)	2.35 (1.03, 5.36)	0.82 (0.27, 2.49)	0.7236	
	Race							0.6843
	White	10/ 34 (29.4)	4.17 (2.48, 7.00)	12/ 34 (35.3)	7.88 (4.74, 13.09)	0.53 (0.26, 1.09)	0.0854	
	Other	7/ 31 (22.6)	8.39 (5.06, 13.93)	9/ 31 (29.0)	12.87 (7.77, 21.32)	0.65 (0.32, 1.33)	0.2420	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for treated bleeds (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for treated bleeds
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for treated bleeds
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	23 (35.4)	25 (38.5)
	Number of bleeds		
	Number	274	293
	Mean (SD)	4.22 (6.970)	4.51 (6.935)
	Median	2.0	1.0
	Q1, Q3	0.0 5.0	0.0 6.0
	Min, Max	0 35	0 29
	Annualized bleeding rate (ABR)		
	Mean (SD)	5.30 (8.540)	9.16 (14.251)
	Median	2.02	2.14
	Q1, Q3	0.00 5.09	0.00 11.66
	Min, Max	0.00 35.51	0.00 59.51
	Model derived ABR [1]		
	Estimate (95% CI)	5.21 (3.46, 7.86)	9.15 (6.10, 13.74)
	Rate Ratio [1]		
	Estimate (95% CI)	0.57 (0.32, 1.01)	
	p-value	0.0560	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	5.21 (3.19, 7.23)	9.12 (5.69, 12.56)
	Treatment difference [2]		
	Estimate (95% CI)	-3.91 (-7.10, -0.73)	
	p-value	0.0161	
	Percentage reduction [3]		
	Estimate (95% CI)	42.87 (13.54, 62.25)	
	p-value	0.0081	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for treated bleeds – Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	1.53 (0.42, 5.59)	8/ 13 (61.5)	3.56 (0.99, 12.78)	0.43 (0.07, 2.65)	0.3620	0.6691
	Adults (Ages 18 to < 75)	14/ 52 (26.9)	6.15 (4.05, 9.34)	17/ 52 (32.7)	10.55 (6.98, 15.95)	0.58 (0.32, 1.05)	0.0720	
	Region							
	Asia	5/ 25 (20.0)	8.67 (5.03, 14.95)	7/ 25 (28.0)	13.52 (7.87, 23.24)	0.64 (0.30, 1.38)	0.2566	0.8114
	Europe	9/ 20 (45.0)	3.89 (1.77, 8.56)	8/ 20 (40.0)	7.05 (3.26, 15.26)	0.55 (0.18, 1.66)	0.2907	
	Middle East	4/ 10 (40.0)	2.84 (0.88, 9.15)	5/ 10 (50.0)	9.26 (3.03, 28.28)	0.31 (0.06, 1.54)	0.1519	
	North America	5/ 10 (50.0)	1.72 (0.69, 4.30)	5/ 10 (50.0)	2.35 (0.90, 6.16)	0.73 (0.19, 2.76)	0.6467	
	Race							
	White	15/ 34 (44.1)	3.35 (1.83, 6.13)	14/ 34 (41.2)	7.13 (3.96, 12.82)	0.47 (0.20, 1.09)	0.0794	0.5945
	Other	8/ 31 (25.8)	7.25 (4.22, 12.46)	11/ 31 (35.5)	11.38 (6.64, 19.51)	0.64 (0.30, 1.37)	0.2468	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for untreated bleeds (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for untreated bleeds
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for untreated bleeds
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	44 (67.7)	51 (78.5)
	Number of bleeds		
	Number	55	36
	Mean (SD)	0.85 (2.202)	0.55 (2.236)
	Median	0.0	0.0
	Q1, Q3	0.0 1.0	0.0 0.0
	Min, Max	0 15	0 17
	Annualized bleeding rate (ABR)		
	Mean (SD)	0.98 (2.494)	1.10 (4.431)
	Median	0.00	0.00
	Q1, Q3	0.00 1.01	0.00 0.00
	Min, Max	0.00 15.13	0.00 33.75
	Model derived ABR [1]		
	Estimate (95% CI)	0.98 (0.53, 1.79)	1.10 (0.59, 2.08)
	Rate Ratio [1]		
	Estimate (95% CI)	0.88 (0.37, 2.13)	
	p-value	0.7825	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	0.98 (0.38, 1.58)	1.10 (0.03, 2.18)
	Treatment difference [2]		
	Estimate (95% CI)	-0.13 (-1.32, 1.07)	
	p-value	0.8352	
	Percentage reduction [3]		
	Estimate (95% CI)	11.48 (-169.92, 70.97)	
	p-value	0.8302	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of Annualized Bleeding Rate for untreated bleeds - Subgroup analysis
MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							0.8097
	Adolescents (Ages 12 to < 18)	11/ 13 (84.6)	0.41 (0.13, 1.36)	9/ 13 (69.2)	0.62 (0.17, 2.20)	0.67 (0.12, 3.81)	0.6490	
	Adults (Ages 18 to < 75)	33/ 52 (63.5)	1.12 (0.57, 2.21)	42/ 52 (80.8)	1.22 (0.60, 2.48)	0.91 (0.34, 2.43)	0.8546	
	Region							0.5844
	Asia	14/ 25 (56.0)	1.44 (0.57, 3.68)	20/ 25 (80.0)	1.76 (0.68, 4.57)	0.82 (0.22, 3.13)	0.7726	
	Europe	15/ 20 (75.0)	0.74 (0.30, 1.83)	15/ 20 (75.0)	0.50 (0.16, 1.55)	1.49 (0.35, 6.37)	0.5868	
	Middle East	7/ 10 (70.0)	1.08 (0.26, 4.59)	6/ 10 (60.0)	1.79 (0.45, 7.10)	0.60 (0.08, 4.45)	0.6214	
	North America	8/ 10 (80.0)	NE (NE, NE)	10/ 10 (100.0)	NE (NE, NE)	NE (NE, NE)	NE	
	Race							0.7179
	White	24/ 34 (70.6)	0.80 (0.37, 1.74)	26/ 34 (76.5)	0.76 (0.32, 1.76)	1.06 (0.34, 3.34)	0.9188	
	Other	20/ 31 (64.5)	1.15 (0.46, 2.90)	25/ 31 (80.6)	1.49 (0.58, 3.80)	0.78 (0.21, 2.89)	0.7049	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Spontaneous (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Spontaneous
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Spontaneous
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	21 (32.3)	29 (44.6)
	Number of bleeds		
	Number	254	236
	Mean (SD)	3.91 (7.211)	3.63 (5.986)
	Median	1.0	1.0
	Q1, Q3	0.0 4.0	0.0 5.0
	Min, Max	0 36	0 28
	Annualized bleeding rate (ABR)		
	Mean (SD)	4.88 (8.700)	7.37 (12.244)
	Median	1.02	1.97
	Q1, Q3	0.00 4.06	0.00 9.56
	Min, Max	0.00 36.53	0.00 55.89
	Model derived ABR [1] Estimate (95% CI)	4.81 (3.14, 7.36)	7.36 (4.82, 11.24)
	Rate Ratio [1] Estimate (95% CI) p-value	0.65 (0.36, 1.19) 0.1642	
	CSR		
	Model derived ABR [2] Estimate (95% CI)	4.81 (2.73, 6.88)	7.34 (4.39, 10.28)
	Treatment difference [2] Estimate (95% CI) p-value	-2.53 (-5.25, 0.19) 0.0687	
	Percentage reduction [3] Estimate (95% CI) p-value	34.45 (-1.26, 57.57) 0.0569	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Spontaneous - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							
	Adolescents (Ages 12 to < 18)	10/ 13 (76.9)	0.96 (0.19, 4.82)	10/ 13 (76.9)	1.71 (0.34, 8.58)	0.56 (0.06, 5.50)	0.6197	0.8146
	Adults (Ages 18 to < 75)	11/ 52 (21.2)	5.78 (3.79, 8.82)	19/ 52 (36.5)	8.77 (5.76, 13.34)	0.66 (0.36, 1.20)	0.1705	
	Region							0.9774
	Asia	5/ 25 (20.0)	8.10 (4.70, 13.95)	7/ 25 (28.0)	11.35 (6.59, 19.53)	0.71 (0.33, 1.54)	0.3894	
	Europe	8/ 20 (40.0)	3.36 (1.52, 7.45)	10/ 20 (50.0)	5.57 (2.53, 12.27)	0.60 (0.20, 1.85)	0.3770	
	Middle East	5/ 10 (50.0)	3.31 (0.64, 17.01)	7/ 10 (70.0)	5.99 (1.20, 30.02)	0.55 (0.06, 5.50)	0.6128	
	North America	3/ 10 (30.0)	1.22 (0.56, 2.63)	5/ 10 (50.0)	2.36 (1.09, 5.09)	0.52 (0.17, 1.54)	0.2346	
	Race							0.6456
	White	12/ 34 (35.3)	3.15 (1.72, 5.75)	16/ 34 (47.1)	5.72 (3.17, 10.35)	0.55 (0.24, 1.28)	0.1655	
	Other	9/ 31 (29.0)	6.63 (3.71, 11.86)	13/ 31 (41.9)	9.16 (5.12, 16.38)	0.72 (0.32, 1.65)	0.4415	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Traumatic (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Traumatic
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Traumatic
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	34 (52.3)	36 (55.4)
	Number of bleeds		
	Number	75	93
	Mean (SD)	1.15 (1.752)	1.43 (2.669)
	Median	0.0	0.0
	Q1, Q3	0.0 2.0	0.0 1.0
	Min, Max	0 9	0 13
	Annualized bleeding rate (ABR)		
	Mean (SD)	1.40 (2.439)	2.90 (5.394)
	Median	0.00	0.00
	Q1, Q3	0.00 2.03	0.00 2.20
	Min, Max	0.00 12.40	0.00 26.68
	Model derived ABR [1]		
	Estimate (95% CI)	1.35 (0.87, 2.09)	2.89 (1.90, 4.40)
	Rate Ratio [1]		
	Estimate (95% CI)	0.47 (0.25, 0.85)	
	p-value	0.0136	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	1.35 (0.82, 1.88)	2.87 (1.58, 4.17)
	Treatment difference [2]		
	Estimate (95% CI)	-1.52 (-2.67, -0.37)	
	p-value	0.0096	
	Percentage reduction [3]		
	Estimate (95% CI)	52.92 (26.92, 69.67)	
	p-value	0.0008	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of Annualized Bleeding Rate for specific type of total bleeds: Traumatic - Subgroup analysis
MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	1.00 (0.27, 3.73)	9/ 13 (69.2)	2.47 (0.68, 8.94)	0.40 (0.06, 2.55)	0.3355	0.8103
	Adults (Ages 18 to < 75)	25/ 52 (48.1)	1.44 (0.91, 2.28)	27/ 52 (51.9)	2.99 (1.93, 4.65)	0.48 (0.25, 0.91)	0.0238	
	Region							0.0241
	Asia	10/ 25 (40.0)	2.01 (1.10, 3.69)	12/ 25 (48.0)	3.92 (2.17, 7.07)	0.51 (0.22, 1.20)	0.1229	
	Europe	13/ 20 (65.0)	1.13 (0.48, 2.67)	11/ 20 (55.0)	1.98 (0.88, 4.49)	0.57 (0.17, 1.87)	0.3549	
	Middle East	5/ 10 (50.0)	0.84 (0.33, 2.14)	3/ 10 (30.0)	5.06 (2.41, 10.65)	0.17 (0.05, 0.55)	0.0033	
	North America	6/ 10 (60.0)	0.71 (0.27, 1.85)	10/ 10 (100.0)	0.00 (0.00, 0.00)	206E9 (206E9, 206E9)	NE	
	Race							0.8962
	White	20/ 34 (58.8)	0.96 (0.50, 1.86)	21/ 34 (61.8)	2.16 (1.16, 4.00)	0.45 (0.18, 1.10)	0.0798	
	Other	14/ 31 (45.2)	1.77 (1.00, 3.13)	15/ 31 (48.4)	3.70 (2.13, 6.44)	0.48 (0.22, 1.06)	0.0685	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Joint (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Joint
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Joint
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	24 (36.9)	28 (43.1)
	Number of bleeds		
	Number	251	223
	Mean (SD)	3.86 (6.968)	3.43 (5.942)
	Median	1.0	1.0
	Q1, Q3	0.0 4.0	0.0 4.0
	Min, Max	0 35	0 29
	Annualized bleeding rate (ABR)		
	Mean (SD)	4.85 (8.472)	6.97 (12.160)
	Median	1.02	1.96
	Q1, Q3	0.00 4.07	0.00 8.07
	Min, Max	0.00 35.51	0.00 57.88
	Model derived ABR [1]		
	Estimate (95% CI)	4.77 (3.11, 7.31)	6.97 (4.55, 10.66)
	Rate Ratio [1]		
	Estimate (95% CI)	0.68 (0.37, 1.25)	
	p-value	0.2182	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	4.77 (2.76, 6.79)	6.94 (4.02, 9.87)
	Treatment difference [2]		
	Estimate (95% CI)	-2.17 (-4.81, 0.47)	
	p-value	0.1078	
	Percentage reduction [3]		
	Estimate (95% CI)	31.25 (-5.84, 55.34)	
	p-value	0.0888	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Joint - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	0.89 (0.26, 3.03)	10/ 13 (76.9)	0.94 (0.25, 3.58)	0.95 (0.15, 5.78)	0.9522	0.6969
	Adults (Ages 18 to < 75)	15/ 52 (28.8)	5.76 (3.75, 8.83)	18/ 52 (34.6)	8.47 (5.53, 12.97)	0.68 (0.37, 1.24)	0.2099	
	Region							0.8915
	Asia	8/ 25 (32.0)	7.31 (4.07, 13.14)	7/ 25 (28.0)	9.50 (5.28, 17.10)	0.77 (0.34, 1.76)	0.5357	
	Europe	8/ 20 (40.0)	3.74 (1.64, 8.54)	10/ 20 (50.0)	6.38 (2.83, 14.37)	0.59 (0.18, 1.87)	0.3666	
	Middle East	4/ 10 (40.0)	3.86 (1.14, 13.05)	5/ 10 (50.0)	7.39 (2.24, 24.34)	0.52 (0.10, 2.87)	0.4553	
	North America	4/ 10 (40.0)	1.52 (0.67, 3.44)	6/ 10 (60.0)	1.38 (0.52, 3.68)	1.10 (0.31, 3.94)	0.8834	
	Race							0.5576
	White	13/ 34 (38.2)	3.50 (1.88, 6.49)	16/ 34 (47.1)	6.27 (3.42, 11.49)	0.56 (0.23, 1.33)	0.1871	
	Other	11/ 31 (35.5)	6.16 (3.45, 11.02)	12/ 31 (38.7)	7.74 (4.31, 13.88)	0.80 (0.35, 1.82)	0.5886	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	34 (52.3)	38 (58.5)
	Number of bleeds		
	Number	84	128
	Mean (SD)	1.29 (2.505)	1.97 (4.440)
	Median	0.0	0.0
	Q1, Q3	0.0 1.0	0.0 2.0
	Min, Max	0 13	0 27
	Annualized bleeding rate (ABR)		
	Mean (SD)	1.54 (2.946)	3.99 (9.037)
	Median	0.00	0.00
	Q1, Q3	0.00 2.02	0.00 3.95
	Min, Max	0.00 14.91	0.00 55.40
	Model derived ABR [1]		
	Estimate (95% CI)	1.52 (0.93, 2.48)	3.99 (2.49, 6.38)
	Rate Ratio [1]		
	Estimate (95% CI)	0.38 (0.19, 0.75)	
	p-value	0.0054	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	1.52 (0.81, 2.23)	3.97 (1.80, 6.15)
	Treatment difference [2]		
	Estimate (95% CI)	-2.46 (-4.45, -0.47)	
	p-value	0.0156	
	Percentage reduction [3]		
	Estimate (95% CI)	61.84 (33.55, 78.09)	
	p-value	0.0007	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]	Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age							0.8511
	Adolescents (Ages 12 to < 18)	10/ 13 (76.9)	1.43 (0.34, 5.93)	8/ 13 (61.5)	3.23 (0.79, 13.17)	0.44 (0.06, 3.27)	0.4230	
	Adults (Ages 18 to < 75)	24/ 52 (46.2)	1.54 (0.91, 2.60)	30/ 52 (57.7)	4.17 (2.54, 6.85)	0.37 (0.18, 0.76)	0.0068	
	Region							0.1466
	Asia	8/ 25 (32.0)	2.99 (1.63, 5.49)	9/ 25 (36.0)	7.59 (4.24, 13.59)	0.39 (0.17, 0.91)	0.0300	
	Europe	12/ 20 (60.0)	0.89 (0.40, 2.01)	14/ 20 (70.0)	1.18 (0.51, 2.75)	0.76 (0.24, 2.44)	0.6429	
	Middle East	8/ 10 (80.0)	0.21 (0.04, 1.21)	6/ 10 (60.0)	3.66 (1.16, 11.54)	0.06 (0.01, 0.47)	0.0074	
	North America	6/ 10 (60.0)	0.51 (0.12, 2.18)	9/ 10 (90.0)	0.97 (0.22, 4.16)	0.52 (0.07, 4.13)	0.5389	
	Race							0.7243
	White	20/ 34 (58.8)	0.74 (0.37, 1.47)	25/ 34 (73.5)	1.62 (0.83, 3.14)	0.46 (0.17, 1.19)	0.1077	
	Other	14/ 31 (45.2)	2.38 (1.28, 4.44)	13/ 31 (41.9)	6.60 (3.64, 11.96)	0.36 (0.15, 0.85)	0.0205	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841005 (17APR2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Target joint (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Target joint
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Target joint
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	45 (69.2)	48 (73.8)
	Number of bleeds		
	Number	131	133
	Mean (SD)	2.02 (5.366)	2.05 (4.584)
	Median	0.0	0.0
	Q1, Q3	0.0 1.0	0.0 1.0
	Min, Max	0 26	0 20
	Annualized bleeding rate (ABR)		
	Mean (SD)	2.66 (6.509)	4.16 (9.330)
	Median	0.00	0.00
	Q1, Q3	0.00 1.02	0.00 1.97
	Min, Max	0.00 27.24	0.00 38.86
	Model derived ABR [1]		
	Estimate (95% CI)	2.61 (1.24, 5.53)	4.15 (1.98, 8.74)
	Rate Ratio [1]		
	Estimate (95% CI)	0.63 (0.22, 1.81)	
	p-value	0.3896	
	CSR		
	Model derived ABR [2]		
	Estimate (95% CI)	2.62 (1.07, 4.17)	4.14 (1.89, 6.39)
	Treatment difference [2]		
	Estimate (95% CI)	-1.52 (-3.48, 0.43)	
	p-value	0.1266	
	Percentage reduction [3]		
	Estimate (95% CI)	36.79 (-10.25, 63.76)	
	p-value	0.1060	

ATP: Active Treatment Phase; CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

[3] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Target joint - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)			Routine Prophylaxis During OP (N=65)			Rate Ratio (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			Number (%) of patients without any bleeds n/N (%)	Model derived ABR[1]			
6-month OP vs 12-month ATP	Age									1.0000
	Adolescents (Ages 12 to < 18)	13/ 13 (100.0)	NE (	NE, NE)	13/ 13 (100.0)	NE (	NE, NE)	NE (	NE, NE)	
	Adults (Ages 18 to < 75)	32/ 52 (61.5)	3.27 (	1.59, 6.73)	35/ 52 (67.3)	5.19 (	2.54, 10.62)	0.63 (	0.23, 1.74)	0.3734
	Region									0.7964
	Asia	16/ 25 (64.0)	4.46 (	1.58, 12.54)	16/ 25 (64.0)	5.86 (	2.08, 16.47)	0.76 (	0.18, 3.28)	0.7143
	Europe	14/ 20 (70.0)	2.31 (	0.57, 9.41)	15/ 20 (75.0)	4.09 (	1.03, 16.23)	0.56 (	0.08, 4.04)	0.5687
	Middle East	8/ 10 (80.0)	0.78 (	0.08, 7.82)	8/ 10 (80.0)	3.80 (	0.44, 33.12)	0.20 (	0.01, 4.85)	0.3255
	North America	7/ 10 (70.0)	0.51 (	0.14, 1.89)	9/ 10 (90.0)	0.39 (	0.07, 2.14)	1.30 (	0.15, 11.10)	0.8124
	Race									0.6596
	White	23/ 34 (67.6)	1.72 (	0.61, 4.81)	26/ 34 (76.5)	3.64 (	1.34, 9.90)	0.47 (	0.11, 1.99)	0.3060
Other	22/ 31 (71.0)	3.58 (	1.22, 10.56)	22/ 31 (71.0)	4.73 (	1.60, 13.93)	0.76 (	0.16, 3.50)	0.7228	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: E7841005 (17APR2023)
 Follow-up duration of patients without any bleeds (Days)
 MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	176.63 (25.841)	179.42 (5.187)
	Median	183.00	182.00
	Q1, Q3	183.00, 183.00	178.00, 183.00
	Min, Max	28.0, 183.0	166.0, 183.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
 Follow-up duration defined as phase end date - phase start date.
 For 6-month OP vs 6-month ATP: min(phase end date - phase start date, 183)

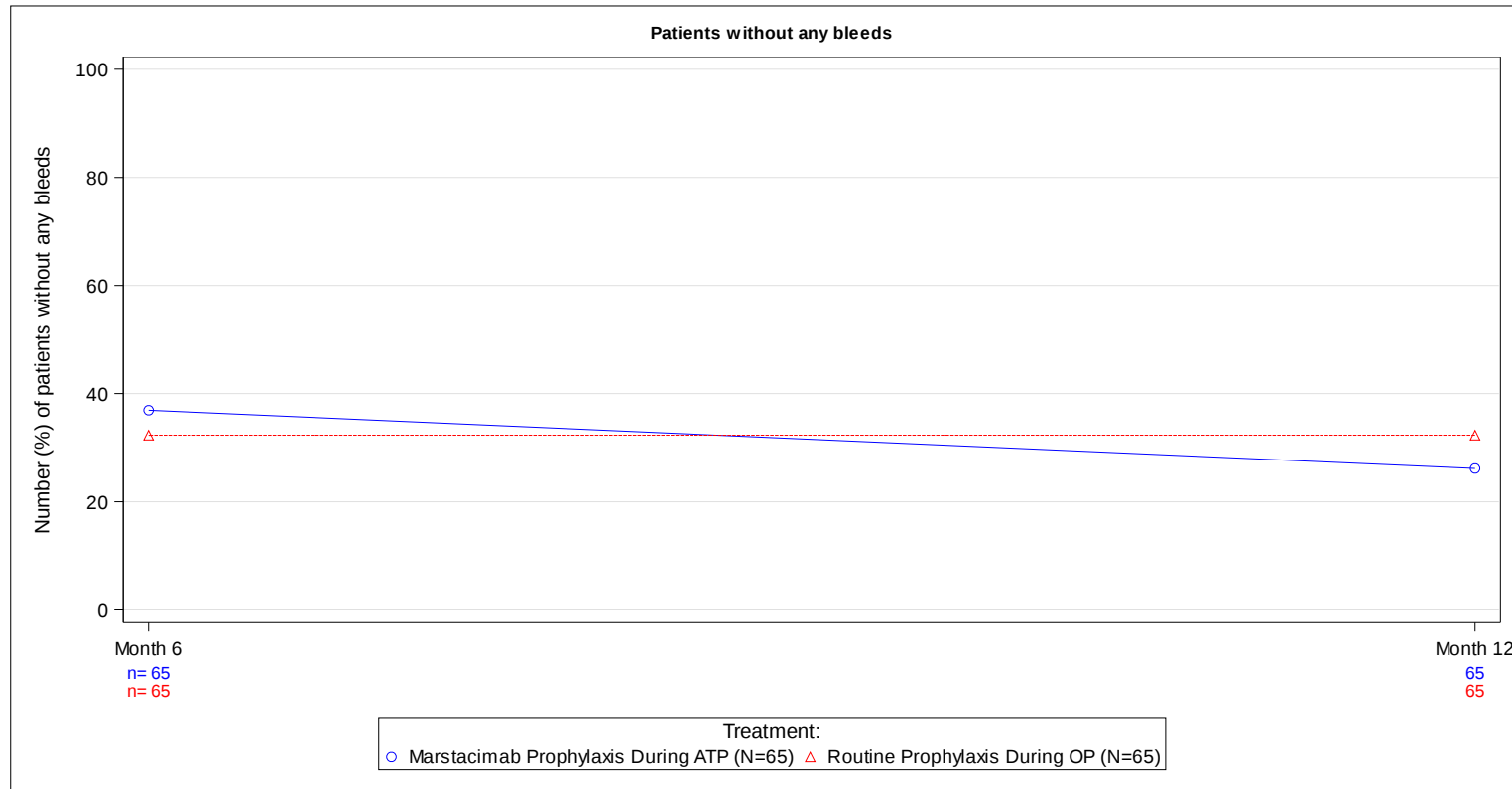
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for patients without any bleeds
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	65 (100.0)	65 (100.0)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
For 6-month OP vs 6-month ATP: Day 183 in phase is used as cutoff.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Graphical Summary of patients without any bleeds
MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of patients without any bleeds
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	Number (%) of patients without any bleeds	24 (36.9)	21 (32.3)
	Relative Risk (95% CI) [1] p-value	1.14 (0.71, 1.84) 0.5809	
	Odds Ratio (95% CI) [1] p-value	1.23 (0.59, 2.53) 0.5804	
	Risk Difference (95% CI) [1] p-value	4.62 (-11.72, 20.95) 0.5798	
6-month OP vs 12-month ATP	Number (%) of patients without any bleeds	17 (26.2)	21 (32.3)
	Relative Risk (95% CI) [1] p-value	0.81 (0.47, 1.39) 0.4424	
	Odds Ratio (95% CI) [1] p-value	0.74 (0.35, 1.59) 0.4412	
	Risk Difference (95% CI) [1] p-value	-6.15 (-21.75, 9.45) 0.4395	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
For 6-month OP vs 6-month ATP: Day 183 in phase is used as cutoff.
[1] Calculated using normal approximation (Wald).

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of patients without any bleeds - Subgroup analysis
MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP(N=65) n/N (%)	Routine Prophylaxis During OP(N=65) n/N (%)	Relative Risk (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
6-month OP vs 6-month ATP	Age					0.4173
	Adolescents (Ages 12 to < 18)	10/ 13 (76.9)	7/ 13 (53.8)	1.43 (0.80, 2.56)	0.2319	
	Adults (Ages 18 to < 75)	14/ 52 (26.9)	14/ 52 (26.9)	1.00 (0.53, 1.88)	1.0000	
	Region					0.8936
	Asia	7/ 25 (28.0)	6/ 25 (24.0)	1.17 (0.46, 2.98)	0.7476	
	Europe	7/ 20 (35.0)	7/ 20 (35.0)	1.00 (0.43, 2.33)	1.0000	
	Middle East	5/ 10 (50.0)	3/ 10 (30.0)	1.67 (0.54, 5.17)	0.3763	
	North America	5/ 10 (50.0)	5/ 10 (50.0)	1.00 (0.42, 2.40)	1.0000	
	Race					0.8051
	White	13/ 34 (38.2)	12/ 34 (35.3)	1.08 (0.58, 2.02)	0.8016	
	Other	11/ 31 (35.5)	9/ 31 (29.0)	1.22 (0.59, 2.53)	0.5884	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
For 6-month OP vs 6-month ATP: Day 183 in phase is used as cutoff.

[1] Calculated using normal approximation (Wald).

[2] Based on test for heterogeneity of the relative risks using Cochran's Q statistic.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of patients with 0 Target Joints (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	176.63 (25.841)	179.42 (5.187)
	Median	183.00	182.00
	Q1, Q3	183.00, 183.00	178.00, 183.00
	Min, Max	28.0, 183.0	166.0, 183.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	333.45 (75.228)	182.08 (7.944)
	Median	360.00	182.00
	Q1, Q3	359.00, 363.00	178.00, 188.00
	Min, Max	28.0, 379.0	166.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.
For 6-month OP vs 6-month ATP: min(phase end date - phase start date, 183)

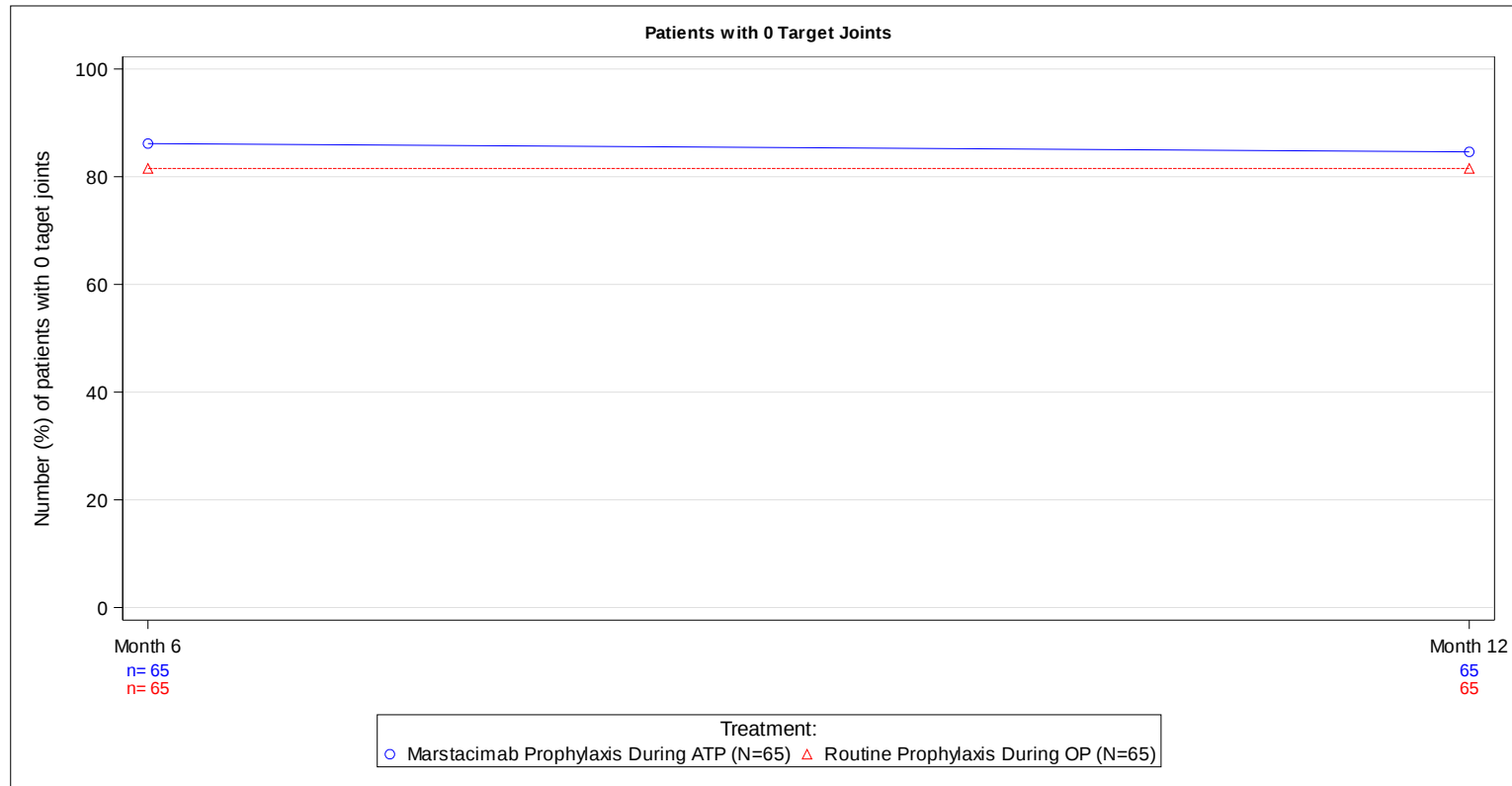
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for patients with 0 Target Joints
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	65 (100.0)	65 (100.0)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
For 6-month OP vs 6-month ATP: Day 183 in phase is used as cutoff.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of patients with 0 Target Joints
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 A target joint is defined as a major joint into which repeated bleeds occur (three or more spontaneous bleeds into a single joint within a consecutive 6-month period).
 OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of patients with 0 Target Joints
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	Number (%) of patients with 0 target joints	56 (86.2)	53 (81.5)
	Relative Risk (95% CI) [1]	1.06 (0.91, 1.23)	
	p-value	0.4756	
	Odds Ratio (95% CI) [1]	1.41 (0.55, 3.62)	
	p-value	0.4759	
6-month OP vs 12-month ATP	Risk Difference (95% CI) [1]	4.62 (-8.01, 17.24)	
	p-value	0.4738	
	Number (%) of patients with 0 target joints	55 (84.6)	53 (81.5)
	Relative Risk (95% CI) [1]	1.04 (0.89, 1.21)	
	p-value	0.6402	
	Odds Ratio (95% CI) [1]	1.25 (0.50, 3.13)	
	p-value	0.6403	
	Risk Difference (95% CI) [1]	3.08 (-9.80, 15.96)	
	p-value	0.6396	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
For 6-month OP vs 6-month ATP: Day 183 in phase is used as cutoff.
A target joint is defined as a major joint into which repeated bleeds occur (three or more spontaneous bleeds into a single joint within a consecutive 6-month period).
[1] Calculated using normal approximation (Wald).

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with 0 Target Joints - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP(N=65) n/N (%)	Routine Prophylaxis During OP(N=65) n/N (%)	Relative Risk (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
6-month OP vs 6-month ATP	Age					NE
	Adolescents (Ages 12 to < 18)	13/ 13 (100.0)	13/ 13 (100.0)	NE (NE, NE)	NE	0.4649
	Adults (Ages 18 to < 75)	43/ 52 (82.7)	40/ 52 (76.9)	1.08 (0.89, 1.31)		
	Region					0.8480
	Asia	20/ 25 (80.0)	19/ 25 (76.0)	1.05 (0.78, 1.41)	0.7331	0.8481
	Europe	17/ 20 (85.0)	15/ 20 (75.0)	1.13 (0.83, 1.55)	0.4331	
	Middle East	9/ 10 (90.0)	9/ 10 (90.0)	1.00 (0.75, 1.34)	1.0000	
	North America	10/ 10 (100.0)	10/ 10 (100.0)	NE (NE, NE)	NE	
	Race					
	White	30/ 34 (88.2)	28/ 34 (82.4)	1.07 (0.88, 1.31)	0.4950	
	Other	26/ 31 (83.9)	25/ 31 (80.6)	1.04 (0.83, 1.31)	0.7398	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

For 6-month OP vs 6-month ATP: Day 183 in phase is used as cutoff.

A target joint is defined as a major joint into which repeated bleeds occur (three or more spontaneous bleeds into a single joint within a consecutive 6-month period).

[1] Calculated using normal approximation (Wald).

[2] Based on test for heterogeneity of the relative risks using Cochran's Q statistic.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Anhang 4-G1.3: Faktor-Ersatztherapie

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Annualized Infusion Rate (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	338.82 (69.620)	191.97 (11.928)
	Median	358.00	191.00
	Q1, Q3	355.00, 359.00	185.00, 197.00
	Min, Max	22.0, 372.0	173.0, 252.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized Infusion Rate
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized Infusion Rate
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any infusions	21 (32.3)	0 (0.0)
	Number of infusions		
	Mean (SD)	6.68 (9.284)	66.88 (18.839)
	Annualized infusion rate (AIR)		
	Mean (SD)	8.06 (12.026)	127.37 (35.793)
	Model derived AIR [1]		
	Estimate (95% CI)	7.78 (6.11, 9.91)	127.37 (102.17, 158.78)
	Rate Ratio [1]		
	Estimate (95% CI)	0.06 (0.04, 0.08)	
	p-value	<.0001	
CSR	Treatment difference [2]		
	Estimate (95% CI)	-119.38 (-127.74, -111.01)	
	p-value	<.0001	
	Percentage reduction [3]		
	Estimate	93.9	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase; SD: Standard Deviation

CSR: same model as for Annualized Bleeding Rate (ABR)

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on paired t-test.

[3] (1- mean AIR Marstacimab Prophylaxis During ATP/mean AIR Routine Prophylaxis During OP) x 100.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of Annualized Infusion Rate - Subgroup analysis
MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value [1]	Interaction p-Value [2]
		Number of patients without any infusions n/N (%)	Model derived AIR [1]	Number of patients without any infusions n/N (%)	Model derived AIR [1]			
6-month OP vs 12-month ATP	Age							0.0055
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	3.04 (1.63, 5.68)	0/ 13 (0.0)	136.1 (79.05, 234.3)	0.02 (0.01, 0.05)	<.0001	
	Adults (Ages 18 to < 75)	12/ 52 (23.1)	9.01 (7.00, 11.59)	0/ 52 (0.0)	125.2 (99.52, 157.5)	0.07 (0.05, 0.10)	<.0001	
	Region							0.0331
	Asia	4/ 25 (16.0)	12.45 (8.93, 17.38)	0/ 25 (0.0)	131.5 (96.71, 178.8)	0.09 (0.06, 0.15)	<.0001	
	Europe	9/ 20 (45.0)	5.91 (3.63, 9.62)	0/ 20 (0.0)	130.9 (84.81, 201.9)	0.05 (0.02, 0.09)	<.0001	
	Middle East	4/ 10 (40.0)	5.09 (2.91, 8.89)	0/ 10 (0.0)	133.6 (81.79, 218.4)	0.04 (0.02, 0.08)	<.0001	
	North America	4/ 10 (40.0)	2.97 (1.84, 4.78)	0/ 10 (0.0)	103.8 (75.50, 142.8)	0.03 (0.02, 0.05)	<.0001	
	Race							0.0664
	White	14/ 34 (41.2)	5.37 (3.81, 7.58)	0/ 34 (0.0)	123.2 (90.90, 166.9)	0.04 (0.03, 0.07)	<.0001	
	Other	7/ 31 (22.6)	10.43 (7.57, 14.37)	0/ 31 (0.0)	132.0 (98.19, 177.3)	0.08 (0.05, 0.12)	<.0001	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Annualized On-Demand Infusion Rate (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	338.82 (69.620)	191.97 (11.928)
	Median	358.00	191.00
	Q1, Q3	355.00, 359.00	185.00, 197.00
	Min, Max	22.0, 372.0	173.0, 252.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Annualized On-Demand Infusion Rate
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized On-Demand Infusion Rate
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Number (%) of patients without any infusions	21 (32.3)	23 (35.4)
	Number of infusions		
	Mean (SD)	6.62 (9.204)	6.69 (10.876)
	Annualized infusion rate (AIR)		
	Mean (SD)	7.98 (11.897)	12.88 (21.247)
	Model derived AIR [1]		
	Estimate (95% CI)	7.88 (5.22, 11.89)	12.88 (8.56, 19.36)
	Rate Ratio [1]		
	Estimate (95% CI)	0.61 (0.34, 1.09)	
	p-value	0.0967	
CSR	Treatment difference [2]		
	Estimate (95% CI)	-4.96 (-9.52, -0.40)	
	p-value	0.0329	
	Percentage reduction [3]		
	Estimate	38.6	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase; SD: Standard Deviation

CSR: same model as for Annualized Bleeding Rate (ABR)

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on paired t-test.

[3] (1- mean AIR Marstacimab Prophylaxis During ATP/mean AIR Routine Prophylaxis During OP) x 100.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of Annualized On-Demand Infusion Rate - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=65)		Rate Ratio (95% CI) [1]	p-Value [1]	Interaction p-Value [2]
		Number of patients without any infusions n/N (%)	Model derived AIR [1]	Number of patients without any infusions n/N (%)	Model derived AIR [1]			
6-month OP vs 12-month ATP	Age							0.9152
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	2.97 (0.82, 10.78)	7/ 13 (53.8)	4.49 (1.22, 16.46)	0.66 (0.11, 4.12)	0.6572	
	Adults (Ages 18 to < 75)	12/ 52 (23.1)	9.12 (6.01, 13.86)	16/ 52 (30.8)	14.97 (9.90, 22.65)	0.61 (0.34, 1.10)	0.0987	
	Region							0.8076
	Asia	4/ 25 (16.0)	12.43 (7.21, 21.41)	6/ 25 (24.0)	21.27 (12.41, 36.43)	0.58 (0.27, 1.26)	0.1690	
	Europe	9/ 20 (45.0)	6.14 (2.74, 13.77)	8/ 20 (40.0)	8.18 (3.68, 18.16)	0.75 (0.24, 2.34)	0.6209	
	Middle East	4/ 10 (40.0)	5.09 (1.69, 15.30)	4/ 10 (40.0)	11.58 (3.87, 34.62)	0.44 (0.09, 2.08)	0.2993	
	North America	4/ 10 (40.0)	2.98 (1.22, 7.26)	5/ 10 (50.0)	2.64 (1.00, 6.95)	1.13 (0.30, 4.20)	0.8586	
	Race							0.8721
	White	14/ 34 (41.2)	5.55 (3.04, 10.14)	14/ 34 (41.2)	8.52 (4.68, 15.48)	0.65 (0.28, 1.52)	0.3227	
	Other	7/ 31 (22.6)	10.45 (6.09, 17.93)	9/ 31 (29.0)	17.67 (10.35, 30.18)	0.59 (0.28, 1.26)	0.1753	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on same GLM with additional factors for subgroup and subgroup*treatment interaction.

Effect measures are calculated if each subgroup level comprises at least 10 patients.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Annualized On-Demand FVIII-Consumption (IU/kg) (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	338.82 (69.620)	191.97 (11.928)
	Median	358.00	191.00
	Q1, Q3	355.00, 359.00	185.00, 197.00
	Min, Max	22.0, 372.0	173.0, 252.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as phase end date - phase start date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Completion Rates for Annualized On-Demand FVIII-Consumption (IU/kg)
 MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	65 (100.0)	65 (100.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of Annualized On-Demand FVIII-Consumption (IU/kg)
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 12-month ATP	Annualized On-Demand FVIII-Consumption Mean (SD)	193.45 (308.740)	355.38 (613.576)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase

Anhang 4-G1.4: Gesundheitszustand

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS) - Follow-up duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	167.14 (39.297)	180.37 (23.917)
	Median	181.00	183.00
	Q1, Q3	176.00, 183.00	179.00, 189.00
	Min, Max	1.0, 196.0	1.0, 205.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	334.17 (84.088)	180.37 (23.917)
	Median	360.00	183.00
	Q1, Q3	359.00, 363.00	179.00, 189.00
	Min, Max	29.0, 479.0	1.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement in phase - the first dose date.
For 6-month ATP: the last measurement up to Day 180 visit - phase start date

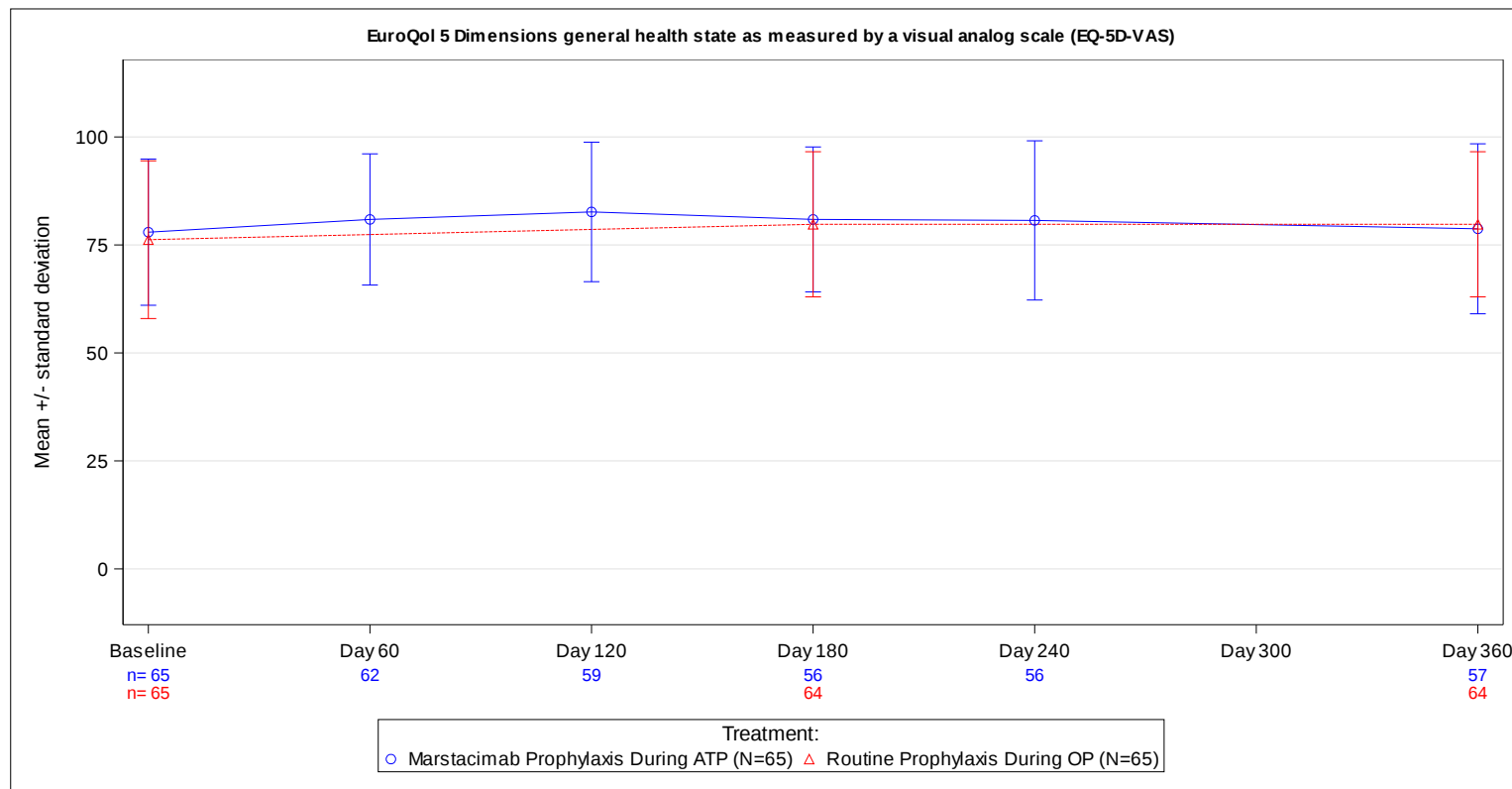
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
Baseline	65 (100.0)	65 (100.0)
Day 60	62 (95.4)	
Day 120	59 (90.8)	
Day 180	56 (86.2)	64 (98.5)
Day 240	56 (86.2)	
Day 360	57 (87.7)	64 (98.5)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Descriptive Statistics of EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
MITT Set

Visit	_ _ _ _ _ Marstacimab Prophylaxis During ATP (N=65) _ _ _ _ _			_ _ _ _ _ Routine Prophylaxis During OP (N=65) _ _ _ _ _		
	Value at Baseline	Value at Visit	Change from Baseline	Value at Baseline	Value at Visit	Change from Baseline
	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)
Baseline	65 77.95 (16.92)	65 77.95 (16.92)		65 76.22 (18.26)	65 76.22 (18.26)	
Day 60	62 77.53 (17.09)	62 80.90 (15.18)	62 3.37 (9.29)			
Day 120	59 77.93 (17.26)	59 82.64 (16.15)	59 4.71 (9.97)			
Day 180	56 76.75 (17.62)	56 80.91 (16.78)	56 4.16 (12.80)	64 76.00 (18.32)	64 79.78 (16.80)	64 3.78 (15.95)
Day 240	56 77.61 (16.07)	56 80.68 (18.43)	56 3.07 (13.04)			
Day 360	57 76.98 (17.53)	57 78.74 (19.68)	57 1.75 (16.15)	64 76.00 (18.32)	64 79.78 (16.80)	64 3.78 (15.95)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
Only observed values are included.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
Day 180	Number (%) of patients imputed	9 (13.8)	1 (1.5)
	Number (%) of patients with improvement	10 (15.4)	14 (21.5)
	Relative Risk (95% CI) [1]	0.70 (0.33, 1.48)	
	p-value	0.3508	
	Odds Ratio (95% CI) [1]	0.65 (0.26, 1.61)	
	p-value	0.3485	
Day 360	Risk Difference (95% CI) [1]	-0.06 (-0.20, 0.07)	
	p-value	0.3445	
	Number (%) of patients imputed	8 (12.3)	1 (1.5)
	Number (%) of patients with improvement	8 (12.3)	14 (21.5)
	Relative Risk (95% CI) [1]	0.59 (0.26, 1.32)	
	p-value	0.2000	
	Odds Ratio (95% CI) [1]	0.53 (0.20, 1.38)	
	p-value	0.1959	
	Risk Difference (95% CI) [1]	-0.09 (-0.22, 0.04)	
	p-value	0.1877	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS) - Subgroup an MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)			Routine Prophylaxis During OP (N=65)			Relative Risk (95% CI) [1]	p-Value [1]	Interaction p-Value [2]
		in Level	imputed (%)	with improvement (%)	in Level	imputed (%)	with improvement (%)			
Day 180	Age									
	Adolescents (Ages 12 to < 18)	13	1 (7.7)	2 (15.4)	13	0 (0.0)	3 (23.1)	0.69 (0.14, 3.50)	0.6583	0.9959
	Adults (Ages 18 to < 75)	52	8 (15.4)	8 (15.4)	52	1 (1.9)	11 (21.2)	0.70 (0.30, 1.64)	0.4106	
	Region									0.5945
	Asia	25	3 (12.0)	6 (24.0)	25	0 (0.0)	7 (28.0)	0.81 (0.30, 2.18)	0.6755	
	Europe	20	5 (25.0)	1 (5.0)	20	0 (0.0)	4 (20.0)	0.25 (0.03, 2.05)	0.1961	
	Middle East	10	1 (10.0)	1 (10.0)	10	1 (10.0)	2 (20.0)	0.54 (0.06, 5.02)	0.5847	
	North America	10	0 (0.0)	2 (20.0)	10	0 (0.0)	1 (10.0)	2.00 (0.21, 18.69)	0.5432	
	Race									0.3137
	White	34	5 (14.7)	3 (8.8)	34	0 (0.0)	7 (20.6)	0.43 (0.12, 1.52)	0.1897	
	Other	31	4 (12.9)	7 (22.6)	31	1 (3.2)	7 (22.6)	0.97 (0.37, 2.51)	0.9460	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.

[1] Calculated using normal approximation (Wald).

[2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Change From Baseline in EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	4.16 (0.19, 8.13)	3.58 (-0.90, 8.05)
	Estimated Median Difference (95% CI)	-0.44 (-6.32, 5.43)	
	p-value	0.8826	
6-month OP vs 12-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	3.70 (0.25, 7.15)	3.58 (-0.90, 8.05)
	Estimated Median Difference (95% CI)	-1.17 (-7.09, 4.76)	
	p-value	0.6999	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Patient Global Impression of Change - Hemophilia (PGIC-H) - Follow-up duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	n (missing)	64 (1)	64 (1)
	Mean (SD)	167.84 (35.379)	180.31 (23.615)
	Median	180.50	183.00
	Q1, Q3	176.00, 183.00	179.00, 189.00
	Min, Max	29.0, 190.0	5.0, 205.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	64 (1)
	Mean (SD)	321.52 (86.332)	180.31 (23.615)
	Median	360.00	183.00
	Q1, Q3	359.00, 363.00	179.00, 189.00
	Min, Max	29.0, 385.0	5.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement in phase - the first dose date.
For 6-month ATP: the last measurement up to Day 180 visit - phase start date

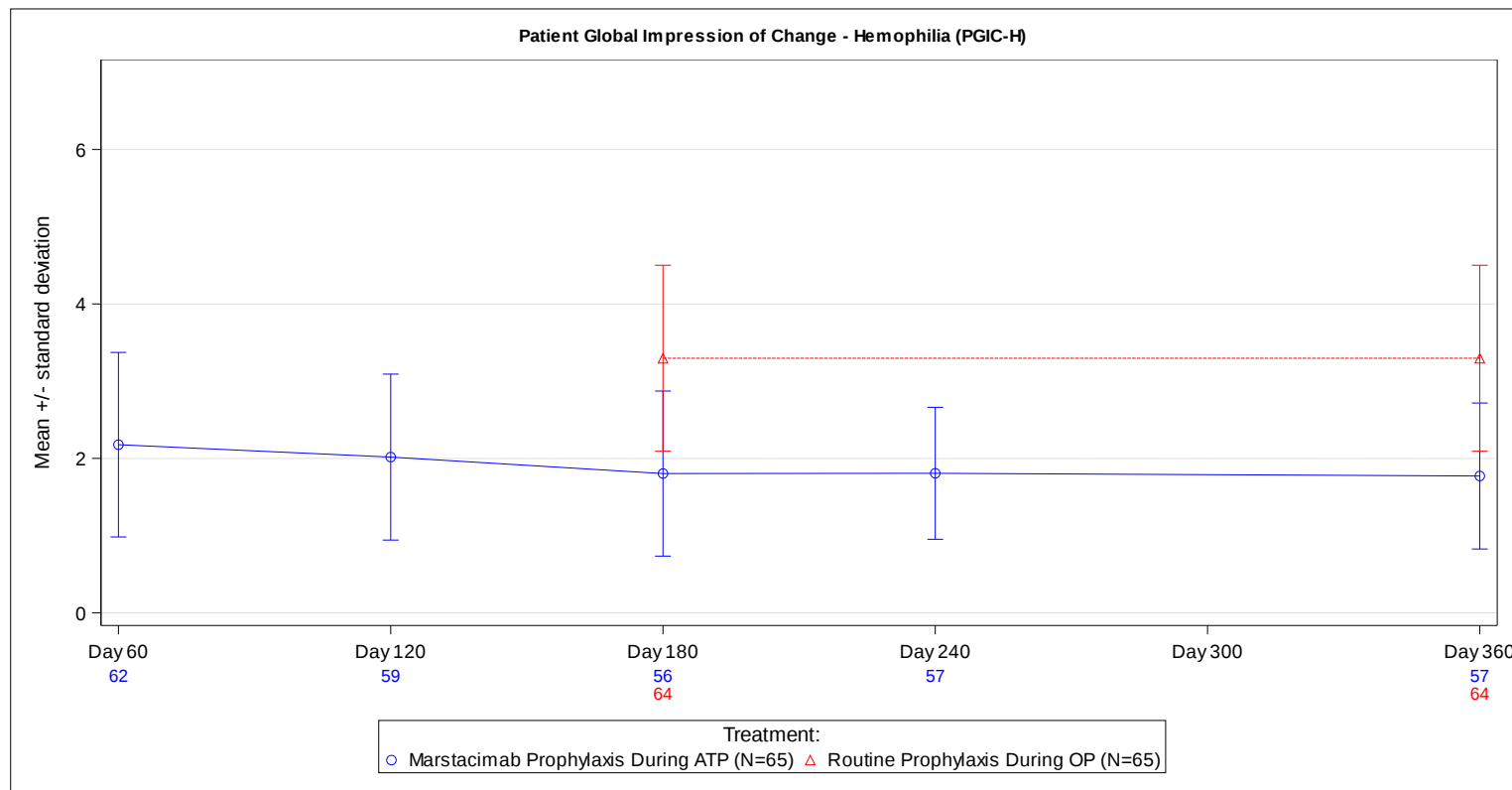
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Patient Global Impression of Change - Hemophilia (PGIC-H)
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
Day 60	62 (95.4)	
Day 120	59 (90.8)	
Day 180	56 (86.2)	64 (98.5)
Day 240	57 (87.7)	
Day 360	57 (87.7)	64 (98.5)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of Patient Global Impression of Change - Hemophilia (PGIC-H)
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Descriptive Statistics of Patient Global Impression of Change - Hemophilia (PGIC-H)
MITT Set

Visit	Marstacimab Prophylaxis During ATP(N=65)						Routine Prophylaxis During OP(N=65)					
	Value at Baseline		Value at Visit		Change from Baseline		Value at Baseline		Value at Visit		Change from Baseline	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Day 60	0	NE (NE)	62	2.18 (1.19)	0	NE (NE)						
Day 120	0	NE (NE)	59	2.02 (1.07)	0	NE (NE)						
Day 180	0	NE (NE)	56	1.80 (1.07)	0	NE (NE)	0	NE (NE)	64	3.30 (1.20)	0	NE (NE)
Day 240	0	NE (NE)	57	1.81 (0.85)	0	NE (NE)						
Day 360	0	NE (NE)	57	1.77 (0.95)	0	NE (NE)	0	NE (NE)	64	3.30 (1.20)	0	NE (NE)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
Only observed values are included.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with Improvement in Patient Global Impression of Change – Hemophilia (PGIC-H)
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)	
Day 180	Number (%) of patients imputed	9 (13.8)	1 (1.5)	
	Number (%) of patients with improvement	59 (90.8)	27 (41.5)	
	Relative Risk (95% CI) [1]	2.14 (1.58, 2.89)		
	p-value	<.0001		
	Odds Ratio (95% CI) [1]	12.45 (4.55, 34.06)		
Day 360	p-value	<.0001		
	Risk Difference (95% CI) [1]	0.48 (0.33, 0.62)		
	p-value	<.0001		
	Number (%) of patients imputed	8 (12.3)	1 (1.5)	
	Number (%) of patients with improvement	61 (93.8)	27 (41.5)	
	Relative Risk (95% CI) [1]	2.21 (1.65, 2.97)		
	p-value	<.0001		
	Odds Ratio (95% CI) [1]	19.14 (6.06, 60.44)		
	p-value	<.0001		
	Risk Difference (95% CI) [1]	0.51 (0.37, 0.65)		
	p-value	<.0001		

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with Improvement in Patient Global Impression of Change - Hemophilia (PGIC-H) - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)			Routine Prophylaxis During OP (N=65)			Relative Risk (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		in Level	imputed (%)	Number of patients with improvement (%)	in Level	imputed (%)	Number of patients with improvement (%)			
Day 180	Age									
	Adolescents (Ages 12 to < 18)	13	1 (7.7)	12 (92.3)	13	0 (0.0)	6 (46.2)	2.00 (1.09, 3.67)	0.0254	0.8159
	Adults (Ages 18 to < 75)	52	8 (15.4)	47 (90.4)	52	1 (1.9)	21 (40.4)	2.17 (1.54, 3.07)	<.0001	
	Region									0.1754
	Asia	25	3 (12.0)	21 (84.0)	25	0 (0.0)	13 (52.0)	1.61 (1.06, 2.44)	0.0263	
	Europe	20	5 (25.0)	19 (95.0)	20	0 (0.0)	6 (30.0)	3.10 (1.56, 6.15)	0.0012	
	Middle East	10	1 (10.0)	10 (100.0)	10	1 (10.0)	6 (60.0)	1.57 (0.95, 2.57)	0.0761	
	North America	10	0 (0.0)	9 (90.0)	10	0 (0.0)	2 (20.0)	4.50 (1.28, 15.81)	0.0190	
	Race									0.0757
	White	34	5 (14.7)	32 (94.1)	34	0 (0.0)	11 (32.4)	2.87 (1.75, 4.72)	<.0001	
	Other	31	4 (12.9)	27 (87.1)	31	1 (3.2)	16 (51.6)	1.64 (1.14, 2.37)	0.0082	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.

[1] Calculated using normal approximation (Wald).

[2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Patient Global Impression of Change - Hemophilia (PGIC-H)
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	1.88 (1.51, 2.25)	3.36 (2.75, 3.98)
	Estimated Median Difference (95% CI)	-1.64 (-2.16, -1.13)	
	p-value	<.0001	
6-month OP vs 12-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	1.60 (1.25, 1.95)	3.36 (2.75, 3.98)
	Estimated Median Difference (95% CI)	-1.97 (-2.26, -1.69)	
	p-value	<.0001	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.

Anhang 4-G1.5: Körperliche Funktionsfähigkeit

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Hemophilia Joint Health Score (HJHS) Total Score - Follow-up duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	163.35 (43.026)	187.12 (35.416)
	Median	181.00	191.00
	Q1, Q3	176.00, 183.00	183.00, 198.00
	Min, Max	29.0, 196.0	1.0, 252.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	65 (0)
	Mean (SD)	341.31 (72.734)	187.12 (35.416)
	Median	360.00	191.00
	Q1, Q3	359.00, 363.00	183.00, 198.00
	Min, Max	29.0, 385.0	1.0, 252.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement in phase - the first dose date.
For 6-month ATP: the last measurement up to Day 180 visit - phase start date

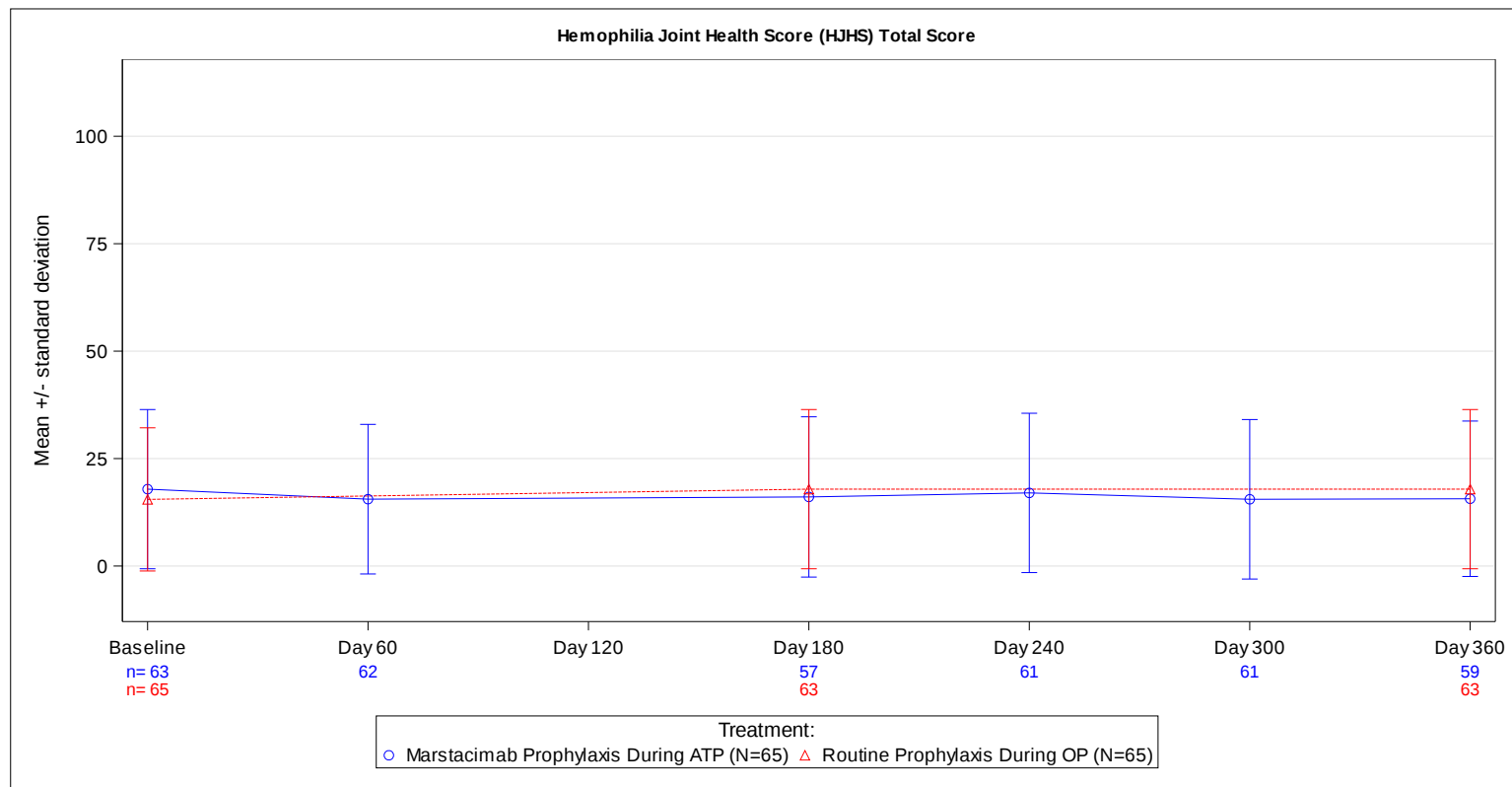
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Hemophilia Joint Health Score (HJHS) Total Score
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
Baseline	63 (96.9)	65 (100.0)
Day 60	62 (95.4)	
Day 180	57 (87.7)	63 (96.9)
Day 240	61 (93.8)	
Day 300	61 (93.8)	
Day 360	59 (90.8)	63 (96.9)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of Hemophilia Joint Health Score (HJHS) Total Score
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Descriptive Statistics of Hemophilia Joint Health Score (HJHS) Total Score
MITT Set

Visit	_ _ _ _ _ Marstacimab Prophylaxis During ATP(N=65) _ _ _ _ _			_ _ _ _ _ Routine Prophylaxis During OP(N=65) _ _ _ _ _		
	Value at Baseline	Value at Visit	Change from Baseline	Value at Baseline	Value at Visit	Change from Baseline
	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)
Baseline	63 17.89 (18.53)	63 17.89 (18.53)		65 15.50 (16.66)	65 15.50 (16.66)	
Day 60	60 16.46 (17.15)	62 15.56 (17.40)	60 -0.43 (4.89)			
Day 180	55 18.76 (19.32)	57 16.08 (18.64)	55 -2.10 (10.53)	63 15.96 (16.71)	63 17.89 (18.53)	63 1.92 (6.75)
Day 240	59 18.15 (19.05)	61 17.01 (18.53)	59 -0.56 (6.08)			
Day 300	59 18.15 (19.05)	61 15.53 (18.56)	59 -2.10 (7.90)			
Day 360	57 17.08 (18.28)	59 15.65 (18.08)	57 -0.88 (5.86)	63 15.96 (16.71)	63 17.89 (18.53)	63 1.92 (6.75)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
Only observed values are included.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 19 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Joint Health Score (HJHS) Total Score
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
Day 180	Number (%) of patients imputed	10 (15.4)	2 (3.1)
	Number (%) of patients with improvement	1 (1.5)	0 (0.0)
	Relative Risk (95% CI) [1]	3.16 (0.13, 76.19)	
	p-value	0.4791	
	Odds Ratio (95% CI) [1]	3.21 (0.13, 80.48)	
	p-value	0.4778	
Day 360	Risk Difference (95% CI) [1]	0.02 (-0.02, 0.05)	
	p-value	0.3133	
	Number (%) of patients imputed	8 (12.3)	2 (3.1)
	Number (%) of patients with improvement	2 (3.1)	0 (0.0)
	Relative Risk (95% CI) [1]	5.48 (0.27, 113.23)	
	p-value	0.2706	
	Odds Ratio (95% CI) [1]	5.68 (0.26, 122.37)	
	p-value	0.2672	
	Risk Difference (95% CI) [1]	0.04 (-0.01, 0.09)	
	p-value	0.1626	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 19 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Joint Health Score (HJHS) Total Score - Subgroup analysis
 MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65)			Routine Prophylaxis During OP (N=65)			Relative Risk (95% CI) [1]	p-Value [1]	Interaction p-Value [2]
		in Level	imputed (%)	with improvement (%)	in Level	imputed (%)	with improvement (%)			
Day 180	Age									
	Adolescents (Ages 12 to < 18)	13	0 (0.0)	0 (0.0)	13	0 (0.0)	0 (0.0)			
	Adults (Ages 18 to < 75)	52	10 (19.2)	1 (1.9)	52	2 (3.8)	0 (0.0)			
	Region									
	Asia	25	3 (12.0)	0 (0.0)	25	1 (4.0)	0 (0.0)			
	Europe	20	6 (30.0)	1 (5.0)	20	1 (5.0)	0 (0.0)			
	Middle East	10	0 (0.0)	0 (0.0)	10	0 (0.0)	0 (0.0)			
	North America	10	1 (10.0)	0 (0.0)	10	0 (0.0)	0 (0.0)			
	Race									
	White	34	7 (20.6)	1 (2.9)	34	1 (2.9)	0 (0.0)			
	Other	31	3 (9.7)	0 (0.0)	31	1 (3.2)	0 (0.0)			

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 [1] Calculated using normal approximation (Wald).
 [2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.
 Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Change From Baseline in Hemophilia Joint Health Score (HJHS) Total Score
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=65)
6-month OP vs 6-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	-0.64 (-2.62, 1.35)	2.15 (-0.37, 4.68)
	Estimated Median Difference (95% CI)	-2.95 (-5.87, -0.03)	
	p-value	0.0477	
6-month OP vs 12-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	-1.08 (-2.88, 0.71)	2.15 (-0.37, 4.68)
	Estimated Median Difference (95% CI)	-2.89 (-5.78, -0.00)	
	p-value	0.0498	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Hemophilia Activities List Version 2 (HAL) Total Score - Follow-up duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
6-month OP vs 6-month ATP	n (missing)	49 (0)	48 (1)
	Mean (SD)	160.57 (45.402)	184.00 (8.111)
	Median	177.00	184.50
	Q1, Q3	176.00, 183.00	181.00, 189.50
	Min, Max	1.0, 190.0	167.0, 205.0
6-month OP vs 12-month ATP	n (missing)	49 (0)	48 (1)
	Mean (SD)	310.00 (95.434)	184.00 (8.111)
	Median	359.00	184.50
	Q1, Q3	289.00, 360.00	181.00, 189.50
	Min, Max	29.0, 370.0	167.0, 205.0

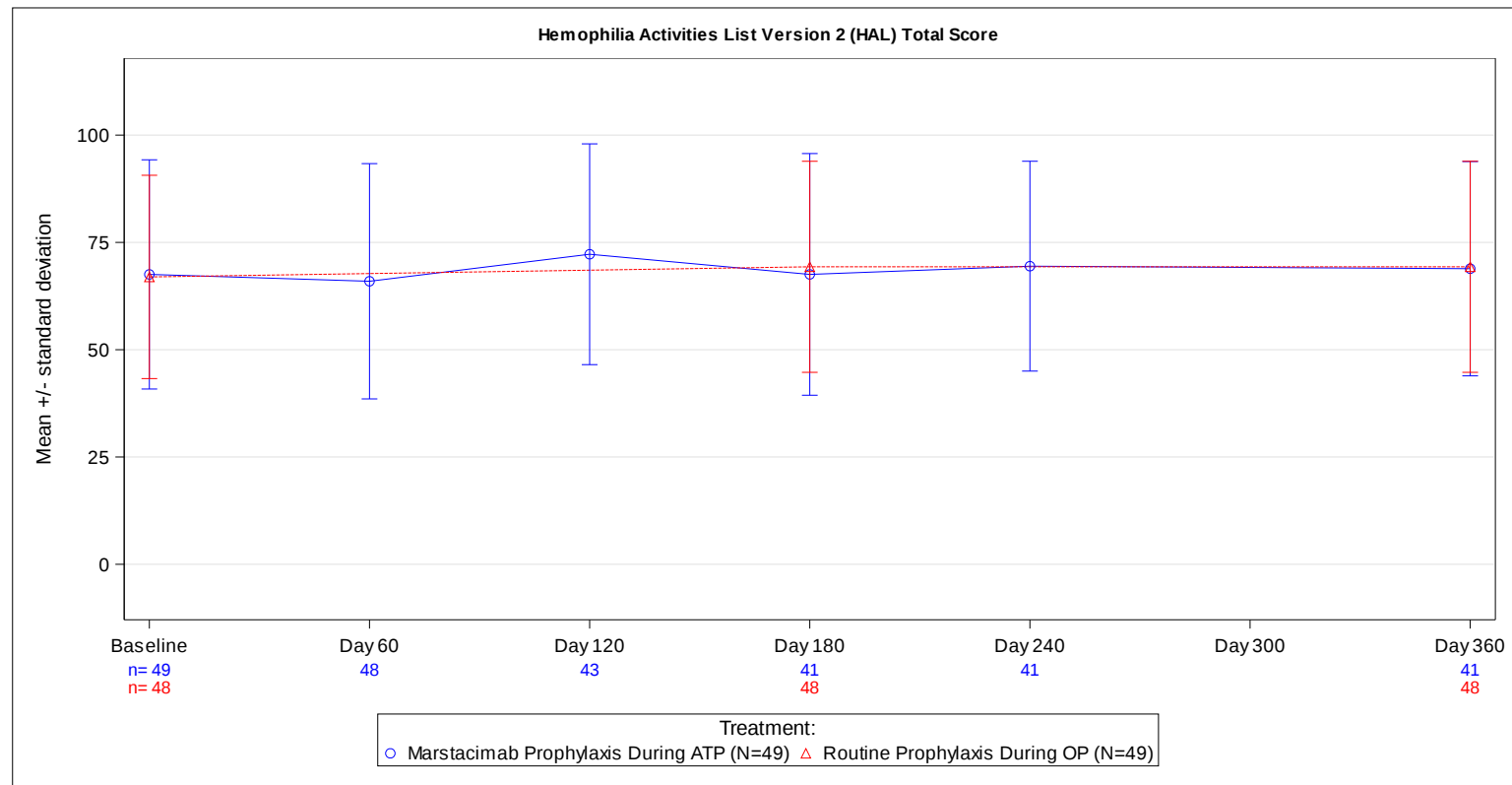
ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement in phase - phase start date.
For 6-month ATP: the last measurement up to Day 180 visit - phase start date
Assessed for participants 17 to < 75 years of age.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Hemophilia Activities List Version 2 (HAL) Total Score
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
Baseline	49 (100.0)	48 (98.0)
Day 60	48 (98.0)	
Day 120	43 (87.8)	
Day 180	41 (83.7)	48 (98.0)
Day 240	41 (83.7)	
Day 360	41 (83.7)	48 (98.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
Assessed for participants 17 to < 75 years of age.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of Hemophilia Activities List Version 2 (HAL) Total Score
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Descriptive Statistics of Hemophilia Activities List Version 2 (HAL) Total Score
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=49)			Routine Prophylaxis During OP (N=49)		
	Value at Baseline	Value at Visit	Change from Baseline	Value at Baseline	Value at Visit	Change from Baseline
	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)
Baseline	49 67.54 (26.70)	49 67.54 (26.70)		48 66.96 (23.68)	48 66.96 (23.68)	
Day 60	48 67.49 (26.98)	48 65.94 (27.41)	48 -1.55 (21.04)			
Day 120	43 66.88 (28.42)	43 72.24 (25.72)	43 5.35 (17.84)			
Day 180	41 66.80 (27.92)	41 67.55 (28.16)	41 0.74 (10.91)	48 66.96 (23.68)	48 69.32 (24.59)	48 2.36 (17.42)
Day 240	41 65.73 (27.05)	41 69.46 (24.45)	41 3.74 (19.54)			
Day 360	41 64.45 (27.77)	41 68.88 (24.97)	41 4.43 (20.17)	48 66.96 (23.68)	48 69.32 (24.59)	48 2.36 (17.42)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
Only observed values are included.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Activities List Version 2 (HAL) Total Score
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
Day 180	Number (%) of patients imputed	8 (16.3)	1 (2.0)
	Number (%) of patients with improvement	4 (8.2)	5 (10.2)
	Relative Risk (95% CI) [1]	0.77 (0.19, 3.18)	
	p-value	0.7175	
	Odds Ratio (95% CI) [1]	0.75 (0.16, 3.51)	
	p-value	0.7178	
Day 360	Risk Difference (95% CI) [1]	-0.02 (-0.13, 0.09)	
	p-value	0.7246	
	Number (%) of patients imputed	8 (16.3)	1 (2.0)
	Number (%) of patients with improvement	7 (14.3)	5 (10.2)
	Relative Risk (95% CI) [1]	1.49 (0.46, 4.84)	
	p-value	0.5087	
	Odds Ratio (95% CI) [1]	1.57 (0.42, 5.89)	
	p-value	0.5070	
	Risk Difference (95% CI) [1]	0.04 (-0.09, 0.18)	
	p-value	0.5029	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).
 Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Activities List Version 2 (HAL) Total Score - Subgroup analysis
 MITT Set

Visit	Subgroup Level	___Marstacimab Prophylaxis During ATP(N=49)___			___Routine Prophylaxis During OP(N=49)___			Relative Risk (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		in Level	imputed (%)	Number of patients with improvement (%)	in Level	imputed (%)	Number of patients with improvement (%)			
Day 180	Age									
	Adults (Ages 18 to < 75)	49	8 (16.3)	4 (8.2)	49	1 (2.0)	5 (10.2)			
	Region									
	Asia	22	3 (13.6)	2 (9.1)	22	1 (4.5)	2 (9.1)			
	Europe	14	5 (35.7)	1 (7.1)	14	0 (0.0)	0 (0.0)			
	Middle East	4	0 (0.0)	0 (0.0)	4	0 (0.0)	2 (50.0)			
	North America	9	0 (0.0)	0 (0.0)	9	0 (0.0)	1 (11.1)			
	Race									
	White	27	5 (18.5)	1 (3.7)	27	0 (0.0)	3 (11.1)			
	Other	22	3 (13.6)	2 (9.1)	22	1 (4.5)	2 (9.1)			

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 [1] Calculated using normal approximation (Wald).
 [2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.
 Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
 Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Change From Baseline in Hemophilia Activities List Version 2 (HAL) Total Score
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
6-month OP vs 6-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	1.02 (-2.51, 4.54)	0.28 (-2.66, 3.22)
	Estimated Median Difference (95% CI)	-0.33 (-4.36, 3.69)	
	p-value	0.8711	
6-month OP vs 12-month ATP	Non-parametric Summary [1]		
	Median Estimate (95% CI)	3.49 (0.04, 6.94)	0.28 (-2.66, 3.22)
	Estimated Median Difference (95% CI)	1.69 (-3.59, 6.97)	
	p-value	0.5305	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.
Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Pediatric Hemophilia Activities List (PEDHAL) Total Score - Follow-up duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
6-month OP vs 6-month ATP	n (missing)	16 (0)	16 (0)
	Mean (SD)	172.63 (31.181)	169.56 (45.471)
	Median	183.00	179.50
	Q1, Q3	177.50, 183.50	175.00, 185.50
	Min, Max	68.0, 190.0	1.0, 193.0
6-month OP vs 12-month ATP	n (missing)	16 (0)	16 (0)
	Mean (SD)	342.19 (47.934)	169.56 (45.471)
	Median	362.50	179.50
	Q1, Q3	359.00, 363.00	175.00, 185.50
	Min, Max	246.0, 385.0	1.0, 193.0

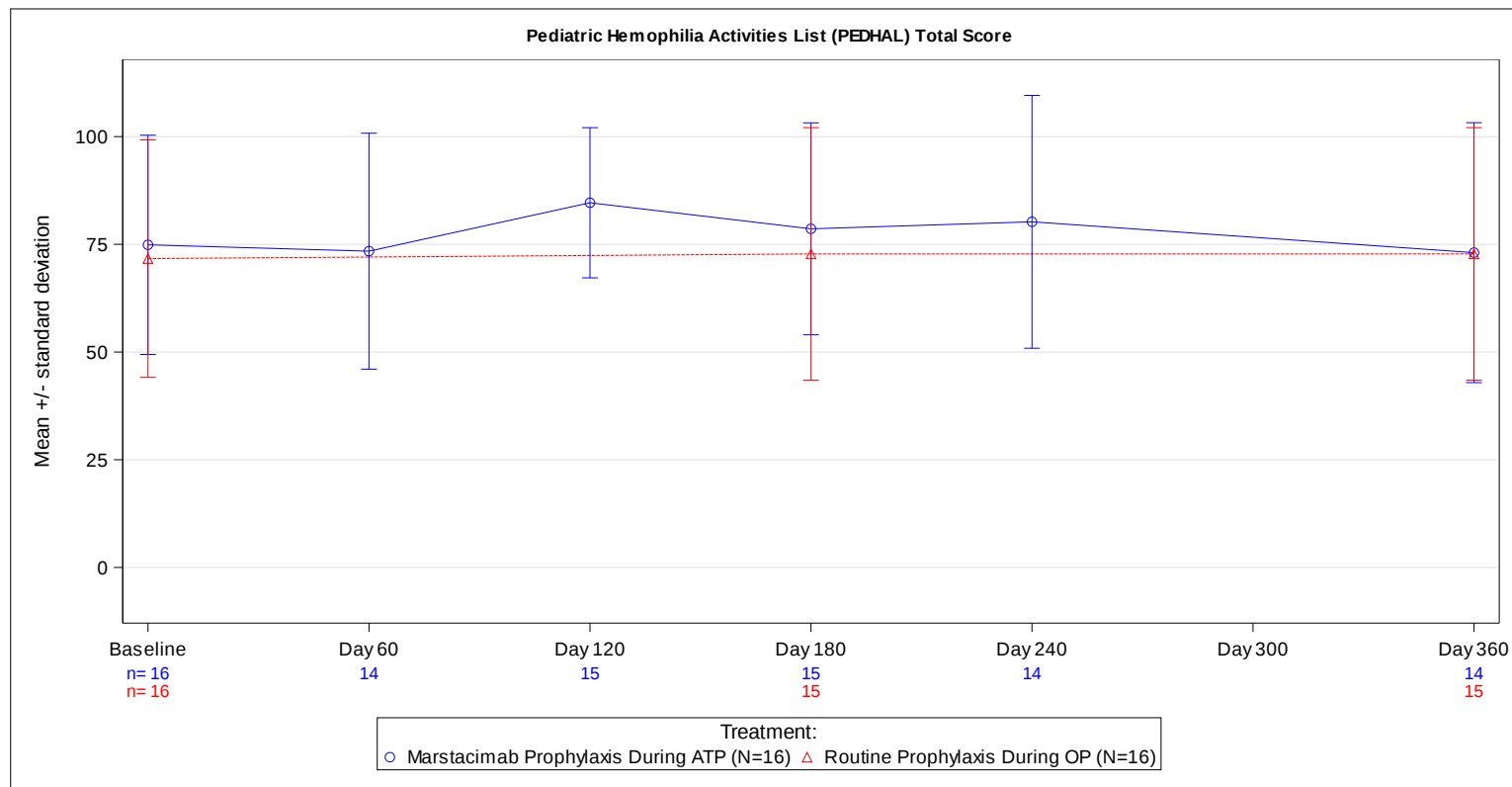
ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement in phase - the first dose date.
For 6-month ATP: the last measurement up to Day 180 visit - phase start date
Assessed for participants 12 to < 17 years of age.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Pediatric Hemophilia Activities List (PEDHAL) Total Score
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
Baseline	16 (100.0)	16 (100.0)
Day 60	14 (87.5)	
Day 120	15 (93.8)	
Day 180	15 (93.8)	15 (93.8)
Day 240	14 (87.5)	
Day 360	14 (87.5)	15 (93.8)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
Assessed for participants 12 to < 17 years of age.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of Pediatric Hemophilia Activities List (PEDHAL) Total Score
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Descriptive Statistics of Pediatric Hemophilia Activities List (PEDHAL) Total Score
 MITT Set

Visit	_ _ _ _ _ Marstacimab Prophylaxis During ATP (N=16) _ _ _ _ _			_ _ _ _ _ Routine Prophylaxis During OP (N=16) _ _ _ _ _		
	Value at Baseline	Value at Visit	Change from Baseline	Value at Baseline	Value at Visit	Change from Baseline
	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)
Baseline	16 74.88 (25.44)	16 74.88 (25.44)		16 71.69 (27.57)	16 71.69 (27.57)	
Day 60	14 73.72 (26.46)	14 73.41 (27.38)	14 -0.31 (28.07)			
Day 120	15 73.21 (25.41)	15 84.65 (17.43)	15 11.44 (18.49)			
Day 180	15 77.21 (24.52)	15 78.60 (24.60)	15 1.39 (24.72)	15 71.86 (28.53)	15 72.77 (29.32)	15 0.90 (21.32)
Day 240	14 78.62 (24.79)	14 80.23 (29.34)	14 1.60 (33.00)			
Day 360	14 79.86 (23.09)	14 73.07 (30.17)	14 -6.80 (32.16)	15 71.86 (28.53)	15 72.77 (29.32)	15 0.90 (21.32)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Activities List (PEDHAL) Total Score
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
Day 180	Number (%) of patients imputed	1 (6.3)	1 (6.3)
	Number (%) of patients with improvement	5 (31.3)	1 (6.3)
	Relative Risk (95% CI) [1]	4.47 (0.56, 35.43)	
	p-value	0.1561	
	Odds Ratio (95% CI) [1]	5.84 (0.57, 59.76)	
	p-value	0.1370	
Day 360	Risk Difference (95% CI) [1]	0.22 (-0.04, 0.48)	
	p-value	0.0975	
	Number (%) of patients imputed	2 (12.5)	1 (6.3)
	Number (%) of patients with improvement	3 (18.8)	1 (6.3)
	Relative Risk (95% CI) [1]	2.55 (0.27, 24.31)	
	p-value	0.4156	
	Odds Ratio (95% CI) [1]	2.86 (0.24, 34.33)	
	p-value	0.4078	
	Risk Difference (95% CI) [1]	0.10 (-0.13, 0.33)	
	p-value	0.3851	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).
 Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Activities List (PEDHAL) Total Score - Subgroup analysis
 MITT Set

Visit	Subgroup Level	___Marstacimab Prophylaxis During ATP(N=16)___			___Routine Prophylaxis During OP(N=16)___			Relative Risk (95% CI)[1]	p-Value[1]	Interaction p-Value[2]
		in Level	imputed (%)	Number of patients with improvement (%)	in Level	imputed (%)	Number of patients with improvement (%)			
Day 180	Age									
	Adolescents (Ages 12 to < 18)	13	1 (7.7)	4 (30.8)	13	0 (0.0)	1 (7.7)			
	Adults (Ages 18 to < 75)	3	0 (0.0)	1 (33.3)	3	1 (33.3)	0 (0.0)			
	Region									
	Asia	3	0 (0.0)	0 (0.0)	3	0 (0.0)	1 (33.3)			
	Europe	6	0 (0.0)	0 (0.0)	6	0 (0.0)	0 (0.0)			
	Middle East	6	1 (16.7)	5 (83.3)	6	1 (16.7)	0 (0.0)			
	North America	1	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)			
	Race									
	White	7	0 (0.0)	0 (0.0)	7	0 (0.0)	0 (0.0)			
	Other	9	1 (11.1)	5 (55.6)	9	1 (11.1)	1 (11.1)			

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 [1] Calculated using normal approximation (Wald).
 [2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.
 Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
 Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Change From Baseline in Pediatric Hemophilia Activities List (PEDHAL) Total Score
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
6-month OP vs 6-month ATP	Non-parametric Summary [1] Median Estimate (95% CI)	7.57 (-2.95, 18.09)	-3.11 (-11.96, 5.74)
	Estimated Median Difference (95% CI)	10.15 (-6.37, 26.67)	
	p-value	0.2286	
6-month OP vs 12-month ATP	Non-parametric Summary [1] Median Estimate (95% CI)	0.41 (-27.55, 28.36)	-3.11 (-11.96, 5.74)
	Estimated Median Difference (95% CI)	3.16 (-28.54, 34.86)	
	p-value	0.8449	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.
Assessed for participants 12 to < 17 years of age.

Anhang 4-G1.6: Gesundheitsbezogene Lebensqualität

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Follow-up duration of Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score - Follow-up duration (Days)
MITT Set

		Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
6-month OP vs 6-month ATP	n (missing)	49 (0)	48 (1)
	Mean (SD)	159.35 (47.051)	184.00 (8.111)
	Median	177.00	184.50
	Q1, Q3	176.00, 183.00	181.00, 189.50
	Min, Max	1.0, 190.0	167.0, 205.0
6-month OP vs 12-month ATP	n (missing)	49 (0)	48 (1)
	Mean (SD)	308.78 (98.151)	184.00 (8.111)
	Median	359.00	184.50
	Q1, Q3	289.00, 360.00	181.00, 189.50
	Min, Max	29.0, 370.0	167.0, 205.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement in phase - the first dose date.
For 6-month ATP: the last measurement up to Day 180 visit - phase start date
Assessed for participants 17 to < 75 years of age.

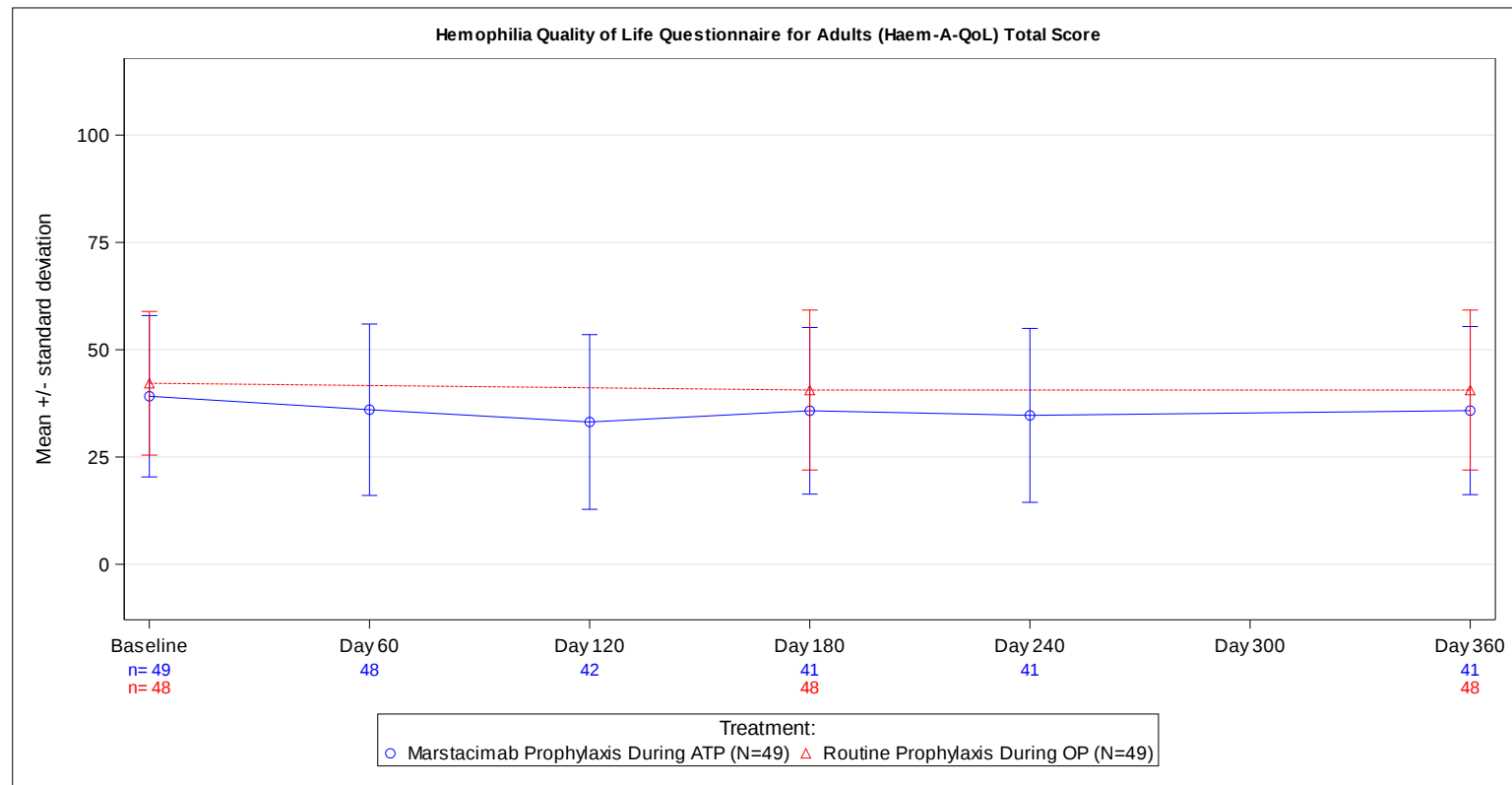
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
Baseline	49 (100.0)	48 (98.0)
Day 60	48 (98.0)	
Day 120	42 (85.7)	
Day 180	41 (83.7)	48 (98.0)
Day 240	41 (83.7)	
Day 360	41 (83.7)	48 (98.0)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
Assessed for participants 17 to < 75 years of age.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Descriptive Statistics of Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
 MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=49)			Routine Prophylaxis During OP (N=49)		
	Value at Baseline	Value at Visit	Change from Baseline	Value at Baseline	Value at Visit	Change from Baseline
	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)
Baseline	49 39.15 (18.80)	49 39.15 (18.80)		48 42.18 (16.74)	48 42.18 (16.74)	
Day 60	48 38.94 (18.94)	48 36.02 (19.97)	48 -2.92 (10.25)			
Day 120	42 39.28 (19.48)	42 33.16 (20.35)	42 -6.12 (10.03)			
Day 180	41 38.94 (18.99)	41 35.77 (19.42)	41 -3.17 (11.03)	48 42.18 (16.74)	48 40.60 (18.63)	48 -1.58 (10.45)
Day 240	41 40.66 (18.90)	41 34.70 (20.26)	41 -5.96 (9.88)			
Day 360	41 41.23 (19.60)	41 35.81 (19.59)	41 -5.42 (9.80)	48 42.18 (16.74)	48 40.60 (18.63)	48 -1.58 (10.45)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
Day 180	Number (%) of patients imputed	8 (16.3)	1 (2.0)
	Number (%) of patients with improvement	8 (16.3)	6 (12.2)
	Relative Risk (95% CI) [1] p-value	1.31 (0.48, 3.61) 0.6020	
	Odds Ratio (95% CI) [1] p-value	1.37 (0.42, 4.45) 0.6003	
	Risk Difference (95% CI) [1] p-value	0.04 (-0.10, 0.18) 0.5942	
Day 360	Number (%) of patients imputed	8 (16.3)	1 (2.0)
	Number (%) of patients with improvement	8 (16.3)	6 (12.2)
	Relative Risk (95% CI) [1] p-value	1.25 (0.44, 3.56) 0.6698	
	Odds Ratio (95% CI) [1] p-value	1.30 (0.39, 4.37) 0.6673	
	Risk Difference (95% CI) [1] p-value	0.03 (-0.11, 0.18) 0.6564	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).
 Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score - Subgroup analysis
MITT Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP(N=49)			Routine Prophylaxis During OP(N=49)			Relative Risk (95% CI) [1]	p-Value[1]	Interaction p-Value[2]
		in Level	imputed (%)	with improvement (%)	in Level	imputed (%)	with improvement (%)			
Day 180	Age									
	Adults (Ages 18 to < 75)	49	8 (16.3)	8 (16.3)	49	1 (2.0)	6 (12.2)			
	Region									
	Asia	22	3 (13.6)	3 (13.6)	22	1 (4.5)	1 (4.5)			
	Europe	14	5 (35.7)	3 (21.4)	14	0 (0.0)	2 (14.3)			
	Middle East	4	0 (0.0)	0 (0.0)	4	0 (0.0)	0 (0.0)			
	North America	9	0 (0.0)	2 (22.2)	9	0 (0.0)	3 (33.3)			
	Race									
	White	27	5 (18.5)	5 (18.5)	27	0 (0.0)	5 (18.5)			
	Other	22	3 (13.6)	3 (13.6)	22	1 (4.5)	1 (4.5)			

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
[1] Calculated using normal approximation (Wald).
[2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Change From Baseline in Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=49)	Routine Prophylaxis During OP (N=49)
6-month OP vs 6-month ATP	Non-parametric Summary [1] Median Estimate (95% CI)	-2.70 (-6.31, 0.91)	-1.05 (-3.40, 1.31)
	Estimated Median Difference (95% CI)	-1.91 (-6.38, 2.57)	
	p-value	0.4033	
6-month OP vs 12-month ATP	Non-parametric Summary [1] Median Estimate (95% CI)	-5.65 (-9.00, -2.30)	-1.05 (-3.40, 1.31)
	Estimated Median Difference (95% CI)	-4.77 (-9.71, 0.16)	
	p-value	0.0579	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.
Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Follow-up duration of Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score - Follow-up duration (Days)
 MITT Set

		Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
6-month OP vs 6-month ATP	n (missing)	16 (0)	16 (0)
	Mean (SD)	179.69 (13.927)	169.56 (45.471)
	Median	183.00	179.50
	Q1, Q3	180.50, 183.50	175.00, 185.50
	Min, Max	130.0, 190.0	1.0, 193.0
6-month OP vs 12-month ATP	n (missing)	16 (0)	16 (0)
	Mean (SD)	356.81 (29.894)	169.56 (45.471)
	Median	363.00	179.50
	Q1, Q3	361.00, 363.00	175.00, 185.50
	Min, Max	247.0, 385.0	1.0, 193.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
 Follow-up duration defined as date of last measurement in phase - the first dose date.
 For 6-month ATP: the last measurement up to Day 180 visit - phase start date
 Assessed for participants 12 to < 17 years of age.

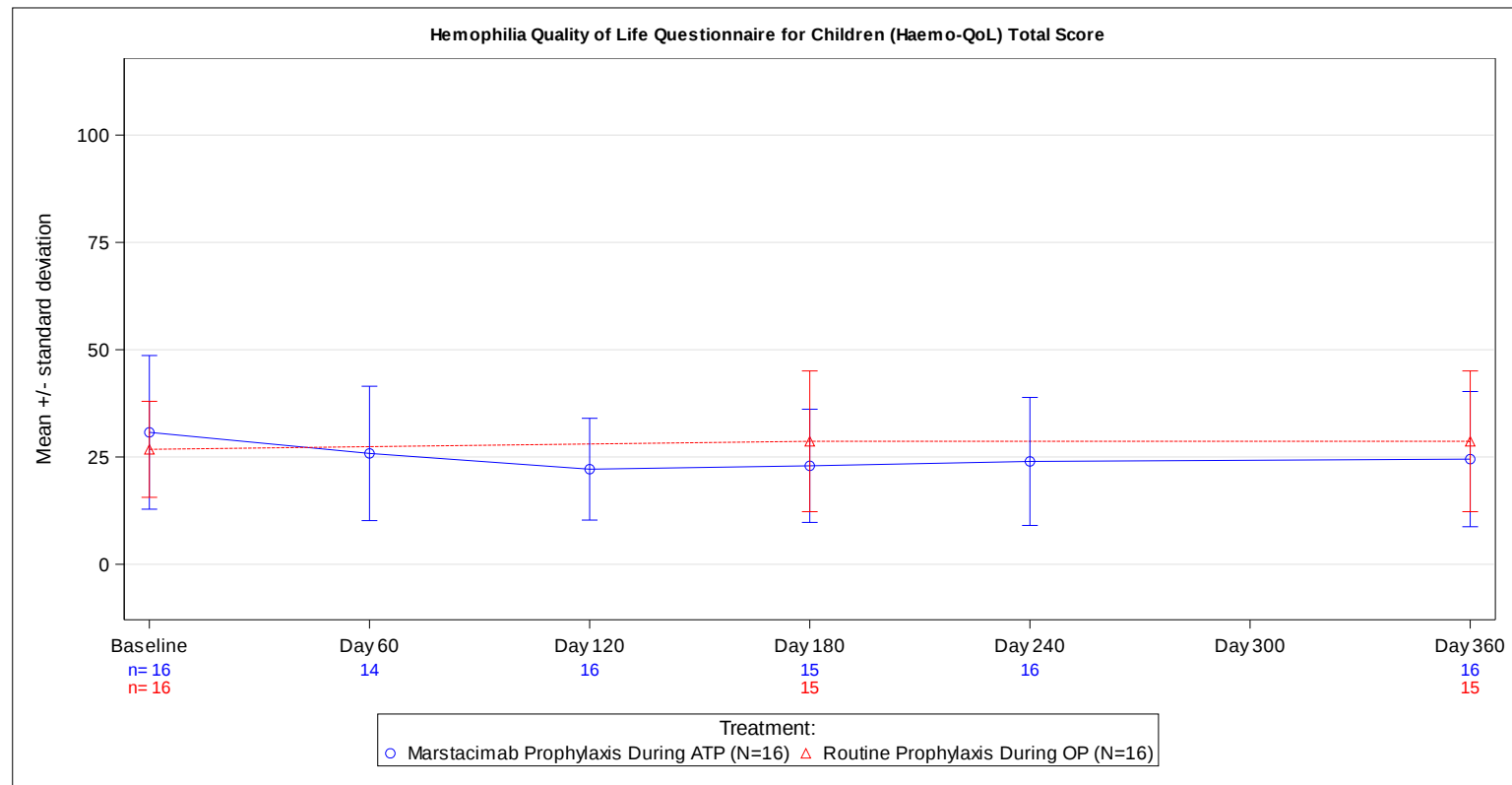
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Completion Rates for Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
Baseline	16 (100.0)	16 (100.0)
Day 60	14 (87.5)	
Day 120	16 (100.0)	
Day 180	15 (93.8)	15 (93.8)
Day 240	16 (100.0)	
Day 360	16 (100.0)	15 (93.8)

ATP: Active Treatment Phase; N: Number of patients; OP: Observational Phase
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
Assessed for participants 12 to < 17 years of age.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Graphical Summary of Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
 MITT Set



ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Descriptive Statistics of Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
 MITT Set

Visit	Marstacimab Prophylaxis During ATP (N=16)			Routine Prophylaxis During OP (N=16)		
	Value at Baseline	Value at Visit	Change from Baseline	Value at Baseline	Value at Visit	Change from Baseline
	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)	n Mean (SD)
Baseline	16 30.74 (17.90)	16 30.74 (17.90)		16 26.79 (11.19)	16 26.79 (11.19)	
Day 60	14 31.22 (17.88)	14 25.83 (15.65)	14 -5.38 (7.06)			
Day 120	16 30.74 (17.90)	16 22.16 (11.86)	16 -8.58 (10.34)			
Day 180	15 29.46 (17.75)	15 22.94 (13.19)	15 -6.52 (10.83)	15 26.26 (11.37)	15 28.66 (16.40)	15 2.40 (13.28)
Day 240	16 30.74 (17.90)	16 23.97 (14.91)	16 -6.78 (11.24)			
Day 360	16 30.74 (17.90)	16 24.50 (15.75)	16 -6.24 (10.57)	15 26.26 (11.37)	15 28.66 (16.40)	15 2.40 (13.28)

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; SD: Standard Deviation
 Only observed values are included.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
 MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
Day 180	Number (%) of patients imputed	1 (6.3)	1 (6.3)
	Number (%) of patients with improvement	4 (25.0)	1 (6.3)
	Relative Risk (95% CI) [1] p-value	4.00 (0.50, 31.98) 0.1912	
	Odds Ratio (95% CI) [1] p-value	5.00 (0.49, 50.83) 0.1738	
	Risk Difference (95% CI) [1] p-value	0.19 (-0.06, 0.43) 0.1306	
Day 360	Number (%) of patients imputed	0 (0.0)	1 (6.3)
	Number (%) of patients with improvement	3 (18.8)	1 (6.3)
	Relative Risk (95% CI) [1] p-value	3.00 (0.35, 25.87) 0.3176	
	Odds Ratio (95% CI) [1] p-value	3.46 (0.32, 37.47) 0.3069	
	Risk Difference (95% CI) [1] p-value	0.13 (-0.10, 0.35) 0.2763	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
 Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
 OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
 [1] Calculated using normal approximation (Wald).
 Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Analysis of patients with >= 15 points Improvement from baseline (Improvement >= 15% of the total scale) in Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score - Subgroup analysis
MITT Set

Visit	Subgroup Level	___Marstacimab Prophylaxis During ATP(N=16)___			___Routine Prophylaxis During OP(N=16)___			Relative Risk (95% CI)[1]	p-Value[1]	Interaction p-Value[2]
		in Level	imputed (%)	Number of patients with improvement (%)	in Level	imputed (%)	Number of patients with improvement (%)			
Day 180	Age									
	Adolescents (Ages 12 to < 18)	13	1 (7.7)	3 (23.1)	13	0 (0.0)	1 (7.7)			
	Adults (Ages 18 to < 75)	3	0 (0.0)	1 (33.3)	3	1 (33.3)	0 (0.0)			
	Region									
	Asia	3	0 (0.0)	0 (0.0)	3	0 (0.0)	0 (0.0)			
	Europe	6	0 (0.0)	0 (0.0)	6	0 (0.0)	1 (16.7)			
	Middle East	6	1 (16.7)	4 (66.7)	6	1 (16.7)	0 (0.0)			
	North America	1	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)			
	Race									
	White	7	0 (0.0)	0 (0.0)	7	0 (0.0)	1 (14.3)			
	Other	9	1 (11.1)	4 (44.4)	9	1 (11.1)	0 (0.0)			

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
[1] Calculated using normal approximation (Wald).
[2] Based on test for heterogeneity of the relative risks using Cochrane's Q statistic.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Non-parametric Analysis of Change From Baseline in Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
MITT Set

Visit		Marstacimab Prophylaxis During ATP (N=16)	Routine Prophylaxis During OP (N=16)
6-month OP vs 6-month ATP	Non-parametric Summary [1] Median Estimate (95% CI)	-5.44 (-11.70, 0.82)	3.40 (-2.56, 9.36)
	Estimated Median Difference (95% CI) p-value	-8.77 (-19.23, 1.70) 0.1006	
6-month OP vs 12-month ATP	Non-parametric Summary [1] Median Estimate (95% CI)	-4.30 (-10.23, 1.62)	3.40 (-2.56, 9.36)
	Estimated Median Difference (95% CI) p-value	-6.33 (-16.61, 3.95) 0.2278	

ATP: Active Treatment Phase; CI: Confidence Interval; N: Number of patients; OP: Observational Phase
Missing values were imputed using multiple imputation methods based on missing at random (MAR) assumption.
OP day 180 also serves as OP day 360 as the treatment duration for OP was 6 months.
[1] Exact confidence interval using Walsh averages, p-value from Wilcoxon Signed Rank test.
Assessed for participants 12 to < 17 years of age.

Anhang 4-G1.7: Verträglichkeit

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Safety Follow-up duration (Days)
All Safety Set

		Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=72)
6-month OP vs 6-month ATP	n (missing)	65 (0)	72 (0)
	Mean (SD)	198.12 (27.032)	201.64 (39.501)
	Median	204.00	210.00
	Q1, Q3	204.00, 204.00	202.50, 217.00
	Min, Max	29.0, 204.0	39.0, 273.0
6-month OP vs 12-month ATP	n (missing)	65 (0)	72 (0)
	Mean (SD)	348.42 (62.493)	201.64 (39.501)
	Median	360.00	210.00
	Q1, Q3	359.00, 363.00	202.50, 217.00
	Min, Max	29.0, 448.0	39.0, 273.0

ATP: Active Treatment Phase; Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; OP: Observational Phase; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as treatment duration + 21.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	32/ 65 (49.2)	13/ 72 (18.1)
6-month OP vs 12-month ATP	46/ 65 (70.8)	13/ 72 (18.1)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	4/ 13 (30.8)
	Adults (Ages 18 to < 75)	23/ 52 (44.2)	9/ 59 (15.3)
	Region		
	Asia	13/ 25 (52.0)	1/ 25 (4.0)
	Europe	9/ 20 (45.0)	9/ 27 (33.3)
	Middle East	5/ 10 (50.0)	1/ 10 (10.0)
	North America	5/ 10 (50.0)	2/ 10 (20.0)
	Race		
	White	16/ 34 (47.1)	12/ 41 (29.3)
	Other	16/ 31 (51.6)	1/ 31 (3.2)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	31/ 65 (47.7)	12/ 72 (16.7)
6-month OP vs 12-month ATP	46/ 65 (70.8)	12/ 72 (16.7)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE excluding PTs related to underlying disease progression - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	9/ 13 (69.2)	4/ 13 (30.8)
	Adults (Ages 18 to < 75)	22/ 52 (42.3)	8/ 59 (13.6)
	Region		
	Asia	13/ 25 (52.0)	1/ 25 (4.0)
	Europe	8/ 20 (40.0)	9/ 27 (33.3)
	Middle East	5/ 10 (50.0)	0/ 10 (0.0)
	North America	5/ 10 (50.0)	2/ 10 (20.0)
	Race		
	White	15/ 34 (44.1)	11/ 41 (26.8)
	Other	16/ 31 (51.6)	1/ 31 (3.2)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious AE
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	3/	65 (4.6)	1/	72 (1.4)
6-month OP vs 12-month ATP	6/	65 (9.2)	1/	72 (1.4)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious AE - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	3/ 52 (5.8)	1/ 59 (1.7)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	2/ 10 (20.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	1/ 10 (10.0)
	Race		
	White	2/ 34 (5.9)	1/ 41 (2.4)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious AE excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	2/ 65 (3.1)	1/ 72 (1.4)
6-month OP vs 12-month ATP	5/ 65 (7.7)	1/ 72 (1.4)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious AE excluding PTs related to underlying disease progression - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	2/ 52 (3.8)	1/ 59 (1.7)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	1/ 10 (10.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	1/ 10 (10.0)
	Race		
	White	1/ 34 (2.9)	1/ 41 (2.4)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe AE
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	2/	65 (3.1)	0/	72 (0.0)
6-month OP vs 12-month ATP	4/	65 (6.2)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe AE - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	2/ 52 (3.8)	0/ 59 (0.0)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	1/ 20 (5.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	1/ 34 (2.9)	0/ 41 (0.0)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe AE excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	2/	65 (3.1)	0/	72 (0.0)
6-month OP vs 12-month ATP	4/	65 (6.2)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	2/ 52 (3.8)	0/ 59 (0.0)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	1/ 20 (5.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	1/ 34 (2.9)	0/ 41 (0.0)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Non-severe AE (Mild, Moderate)
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	31/ 65 (47.7)	13/ 72 (18.1)
6-month OP vs 12-month ATP	46/ 65 (70.8)	13/ 72 (18.1)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe AE excluding PTs related to underlying disease progression - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	2/ 52 (3.8)	0/ 59 (0.0)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	1/ 20 (5.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	1/ 34 (2.9)	0/ 41 (0.0)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Non-severe AE (Mild, Moderate) excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	30/ 65 (46.2)	12/ 72 (16.7)
6-month OP vs 12-month ATP	46/ 65 (70.8)	12/ 72 (16.7)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to discontinuation of study drug
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=72)
	n/N (%)	n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	1/ 65 (1.5)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to discontinuation of study drug excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	1/	65 (1.5)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to discontinuation of study
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	1/	65 (1.5)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to discontinuation of study excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	1/ 65 (1.5)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to death
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	0/	65 (0.0)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to death - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to death excluding PTs related to underlying disease progression
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of AE leading to death excluding PTs related to underlying disease progression - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of COVID-19
All Safety Set

Visit	Marstacimab Prophylaxis During ATP(N=65)	Routine Prophylaxis During OP(N=72)
	n/N (%)	n/N (%)
6-month OP vs 6-month ATP	8/ 65 (12.3)	2/ 72 (2.8)
6-month OP vs 12-month ATP	14/ 65 (21.5)	2/ 72 (2.8)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Overall Summary of COVID-19 - Subgroup analysis
 All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	3/ 13 (23.1)	1/ 13 (7.7)
	Adults (Ages 18 to < 75)	5/ 52 (9.6)	1/ 59 (1.7)
	Region		
	Asia	2/ 25 (8.0)	0/ 25 (0.0)
	Europe	5/ 20 (25.0)	2/ 27 (7.4)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	1/ 10 (10.0)	0/ 10 (0.0)
	Race		
	White	6/ 34 (17.6)	2/ 41 (4.9)
	Other	2/ 31 (6.5)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
 ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
 OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious COVID-19
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious COVID-19 - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe COVID-19
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=72)
	n/N (%)	n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe COVID-19 - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Cardiac arrhythmias
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	0/	65 (0.0)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Cardiac arrhythmias - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Cardiac arrhythmias
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	0/	65 (0.0)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Cardiac arrhythmias - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Cardiac arrhythmias
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Cardiac arrhythmias - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Embolic and thrombotic events (SMQ)
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Embolic and thrombotic events (SMQ) - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Embolic and thrombotic events (SMQ)
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Embolic and thrombotic events (SMQ) - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Embolic and thrombotic events (SMQ)
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Embolic and thrombotic events (SMQ) - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Gastrointestinal varices/Haemorrhoids
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=72)
	n/N (%)	n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Gastrointestinal varices/Haemorrhoids - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Gastrointestinal varices/Haemorrhoids
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	0/	65 (0.0)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Gastrointestinal varices/Haemorrhoids - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Gastrointestinal varices/Haemorrhoids
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=72)
	n/N (%)	n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Gastrointestinal varices/Haemorrhoids - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Haemodynamic oedema, effusions and fluid overload
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	1/	65 (1.5)	0/	72 (0.0)
6-month OP vs 12-month ATP	2/	65 (3.1)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Haemodynamic oedema, effusions and fluid overload - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	1/ 52 (1.9)	0/ 59 (0.0)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Haemodynamic oedema, effusions and fluid overload
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	1/ 65 (1.5)	0/ 72 (0.0)
6-month OP vs 12-month ATP	1/ 65 (1.5)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Haemodynamic oedema, effusions and fluid overload - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	1/ 52 (1.9)	0/ 59 (0.0)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Haemodynamic oedema, effusions and fluid overload
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Haemodynamic oedema, effusions and fluid overload - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Haemorrhages
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	5/ 65 (7.7)	2/ 72 (2.8)
6-month OP vs 12-month ATP	7/ 65 (10.8)	2/ 72 (2.8)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Haemorrhages - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	1/ 13 (7.7)
	Adults (Ages 18 to < 75)	5/ 52 (9.6)	1/ 59 (1.7)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	1/ 20 (5.0)	0/ 27 (0.0)
	Middle East	2/ 10 (20.0)	0/ 10 (0.0)
	North America	2/ 10 (20.0)	2/ 10 (20.0)
	Race		
	White	5/ 34 (14.7)	2/ 41 (4.9)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Haemorrhages
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	2/	65 (3.1)	0/	72 (0.0)
6-month OP vs 12-month ATP	2/	65 (3.1)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Haemorrhages - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	2/ 52 (3.8)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	2/ 10 (20.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	2/ 34 (5.9)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Haemorrhages
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	0/	65 (0.0)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Haemorrhages - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Hepatic disorders
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	1/	65 (1.5)	0/	72 (0.0)
6-month OP vs 12-month ATP	2/	65 (3.1)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Hepatic disorders - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	1/ 52 (1.9)	0/ 59 (0.0)
	Region		
	Asia	1/ 25 (4.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	1/ 31 (3.2)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Hepatic disorders
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Hepatic disorders - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Hepatic disorders
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Hepatic disorders - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Hypersensitivity
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	2/	65 (3.1)	2/	72 (2.8)
6-month OP vs 12-month ATP	3/	65 (4.6)	2/	72 (2.8)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Hypersensitivity - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	2/ 52 (3.8)	2/ 59 (3.4)
	Region		
	Asia	1/ 25 (4.0)	1/ 25 (4.0)
	Europe	1/ 20 (5.0)	1/ 27 (3.7)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	1/ 34 (2.9)	1/ 41 (2.4)
	Other	1/ 31 (3.2)	1/ 31 (3.2)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Hypersensitivity
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Hypersensitivity - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Hypersensitivity
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Hypersensitivity - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Hypertension
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
	n/N (%)		n/N (%)	
6-month OP vs 6-month ATP	0/	65 (0.0)	0/	72 (0.0)
6-month OP vs 12-month ATP	2/	65 (3.1)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Hypertension - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Hypertension
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Hypertension - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Hypertension
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Hypertension - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Injection site reactions
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	8/ 65 (12.3)	0/ 72 (0.0)
6-month OP vs 12-month ATP	8/ 65 (12.3)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Injection site reactions - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	4/ 13 (30.8)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	4/ 52 (7.7)	0/ 59 (0.0)
	Region		
	Asia	4/ 25 (16.0)	0/ 25 (0.0)
	Europe	1/ 20 (5.0)	0/ 27 (0.0)
	Middle East	1/ 10 (10.0)	0/ 10 (0.0)
	North America	2/ 10 (20.0)	0/ 10 (0.0)
	Race		
	White	3/ 34 (8.8)	0/ 41 (0.0)
	Other	5/ 31 (16.1)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Injection site reactions
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Serious Injection site reactions - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Injection site reactions
All Safety Set

Visit	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	0/ 65 (0.0)	0/ 72 (0.0)
6-month OP vs 12-month ATP	0/ 65 (0.0)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of Severe Injection site reactions - Subgroup analysis
All Safety Set

Visit	Subgroup Level	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	Age		
	Adolescents (Ages 12 to < 18)	0/ 13 (0.0)	0/ 13 (0.0)
	Adults (Ages 18 to < 75)	0/ 52 (0.0)	0/ 59 (0.0)
	Region		
	Asia	0/ 25 (0.0)	0/ 25 (0.0)
	Europe	0/ 20 (0.0)	0/ 27 (0.0)
	Middle East	0/ 10 (0.0)	0/ 10 (0.0)
	North America	0/ 10 (0.0)	0/ 10 (0.0)
	Race		
	White	0/ 34 (0.0)	0/ 41 (0.0)
	Other	0/ 31 (0.0)	0/ 31 (0.0)

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Incidence of AE leading to discontinuation of study drug by SOC, PT
All Safety Set

Visit	System Organ Class (SOC) Preferred Term (PT)	Marstacimab Prophylaxis During ATP (N=65)		Routine Prophylaxis During OP (N=72)	
		n/N (%)		n/N (%)	
6-month OP vs 12-month ATP	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/	65 (1.5)	0/	72 (0.0)
	Meningioma	1/	65 (1.5)	0/	72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Incidence of AE leading to discontinuation of study by SOC, PT
All Safety Set

Visit	System Organ Class (SOC) Preferred Term (PT)	Marstacimab Prophylaxis During ATP (N=65)	Routine Prophylaxis During OP (N=72)
		n/N (%)	n/N (%)
6-month OP vs 12-month ATP	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/ 65 (1.5)	0/ 72 (0.0)
	Meningioma	1/ 65 (1.5)	0/ 72 (0.0)

MedDRA v25.1 coding dictionary applied.

ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841005 (17APR2023)
 Overall Summary of frequent AE by SOC, PT (incidence >= 10% or >=10 patients)
 All Safety Set

Visit	System organ class (SOC) / Preferred term (PT)	Marstacimab Prophylaxis During ATP (N=65) n/N (%)	Routine Prophylaxis During OP (N=72) n/N (%)
6-month OP vs 6-month ATP	SOC: Investigations	7/ 65 (10.8)	0/ 72 (0.0)
	SOC: Gastrointestinal disorders	7/ 65 (10.8)	2/ 72 (2.8)
	SOC: Injury, poisoning and procedural complications	7/ 65 (10.8)	3/ 72 (4.2)
	SOC: General disorders and administration site conditions	11/ 65 (16.9)	1/ 72 (1.4)
	SOC: Infections and infestations	12/ 65 (18.5)	4/ 72 (5.6)
	SOC: Infections and infestations - PT:COVID-19	8/ 65 (12.3)	2/ 72 (2.8)
6-month OP vs 12-month ATP	SOC: Investigations	9/ 65 (13.8)	0/ 72 (0.0)
	SOC: Gastrointestinal disorders	10/ 65 (15.4)	2/ 72 (2.8)
	SOC: Injury, poisoning and procedural complications	10/ 65 (15.4)	3/ 72 (4.2)
	SOC: General disorders and administration site conditions	13/ 65 (20.0)	1/ 72 (1.4)
	SOC: Infections and infestations	22/ 65 (33.8)	4/ 72 (5.6)
	SOC: Infections and infestations - PT:COVID-19	14/ 65 (21.5)	2/ 72 (2.8)
	SOC: Musculoskeletal and connective tissue disorders	11/ 65 (16.9)	4/ 72 (5.6)

MedDRA v25.1 coding dictionary applied.
 ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
 OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
All Safety Set

!!! There are no Observations for this Report !!!

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841005 (17APR2023)
Overall Summary of frequent Severe AE (NCI CTCAE grade ≥ 3) by SOC, PT (incidence $\geq 5\%$ or ≥ 10 patients)
All Safety Set

!!! There are no Observations for this Report !!!

MedDRA v25.1 coding dictionary applied.
ATP: Active Treatment Phase; N: Number of patients; n: Number of patients with event; OP: Observational Phase
OP month 6 also serves as OP month 12 as the treatment duration for OP was 6 months. ATP month 6 is up to day 183.

Anhang 4-G2: Ergänzende Daten zur Studie B7841007

Anhang 4-G2.1: Disposition und Baseline-Charakteristika

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (10MAR2023)
 Disposition Events Summary
 Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=45) n (%)
Disposition phase: Screening	
Participants Entered	45 (100.0%)
Discontinued	0 (0.0%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Pregnancy	0 (0.0%)
Protocol Deviation	0 (0.0%)
Screen failure	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	0 (0.0%)
Medication Error Without Associated Adverse Event	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Other	0 (0.0%)
Completed	45 (100.0%)
Ongoing	0 (0.0%)
Disposition phase: Treatment	
Participants Entered	45 (100.0%)
Discontinued	1 (2.2%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Pregnancy	0 (0.0%)
Protocol Deviation	0 (0.0%)
Screen failure	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	1 (2.2%)
Medication Error Without Associated Adverse Event	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Other	0 (0.0%)
Completed	0 (0.0%)
Ongoing	44 (97.8%)
Disposition Phase: Follow-up	
Participants Entered	1 (2.2%)
Discontinued	0 (0.0%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Pregnancy	0 (0.0%)
Protocol Deviation	0 (0.0%)
Screen failure	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	0 (0.0%)
Medication Error Without Associated Adverse Event	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Other	0 (0.0%)
Completed	1 (2.2%)
Ongoing	0 (0.0%)

N: Number of patients; n: Number of patients with non-missing status

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Baseline and Demographic Characteristics
Safety Analysis Set

		Non-Inhibitor Prophylaxis (N=45)
Age (Years)		
Mean (SD)		30.36 (13.64)
Median		29.00
Min, Max		13.00, 58.00
Q1, Q3		18.00, 40.00
n (missing)		45 (0)
Age (Years), n(%)		
<18		10 (22.2%)
18-44		26 (57.8%)
45-64		9 (20.0%)
65-74		0 (0.0%)
>=75		0 (0.0%)
Sex, n(%)		
Male		45 (100.0%)
Race, n(%)		
Black or African American		0 (0.0%)
American Indian or Alaska Native		0 (0.0%)
Asian		18 (40.0%)
Native Hawaiian or Other Pacific Islander		0 (0.0%)
White		27 (60.0%)
Not Reported		0 (0.0%)
Ethnicity, n(%)		
Hispanic or Latino		9 (20.0%)
Not Hispanic or Latino		36 (80.0%)
Baseline eGFR* (mL/min/1.73m^2), n(%)		
missing		4 (8.9%)
>=90		31 (68.9%)
>= 60 to < 90		10 (22.2%)
>= 30 to < 60		0 (0.0%)
<30		0 (0.0%)
Weight (kg)		
Mean (SD)		73.32 (16.64)
Median		73.80
Min, Max		39.00, 128.80
Q1, Q3		60.80, 81.00
n (missing)		45 (0)
Height (cm)		
Mean (SD)		171.50 (6.76)
Median		171.95
Min, Max		156.30, 182.20
Q1, Q3		166.35, 177.30
n (missing)		44 (1)
Body Mass Index (kg/m^2)		
Mean (SD)		24.84 (4.93)
Median		24.29
Min, Max		15.96, 38.88
Q1, Q3		21.70, 27.98
n (missing)		44 (1)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Baseline and Demographic Characteristics
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=45)
Hemophilia Type, n(%)	
Hemophilia A	45 (100.0%)
Hemophilia B	0 (0.0%)
Age Groups, n(%)	
Adolescents (Ages 12 to < 18)	10 (22.2%)
Adults (Ages 18 to < 75)	35 (77.8%)
Age and Hemophilia Type, n(%)	
Adolescents Hem A	10 (22.2%)
Adolescents Hem B	0 (0.0%)
Adults Hem A	35 (77.8%)
Adults Hem B	0 (0.0%)
Family History of Hemophilia, n(%)	
Yes	23 (51.1%)
No	21 (46.7%)
Unknown	1 (2.2%)
Factor VIII Activity at Baseline, n(%)	
missing	0 (0.0%)
< 1%	43 (95.6%)
>= 1%	2 (4.4%)
Factor VIII Inhibitor at Baseline, n(%)	
Positive	0 (0.0%)
Negative	45 (100.0%)
ISTH Disease Severity, n(%)	
Mild	0 (0.0%)
Moderate	0 (0.0%)
Severe	45 (100.0%)
Number of Bleeds (in past 6 months)	
Mean (SD)	5.09 (10.22)
Median	1.00
Min, Max	0.00, 48.00
Q1, Q3	0.00, 5.00
n (missing)	45 (0)
Number of Bleeds (in past 6 months), n(%)	
Number of participants with >= 6 bleeds	10 (22.2%)
Number of participants with < 6 bleeds	35 (77.8%)
Number of Target Joints at Baseline, n(%)	
0	22 (48.9%)
1	10 (22.2%)
2	9 (20.0%)
>=3	4 (8.9%)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilie A
 Datacut: B7841007 (10MAR2023)
 Baseline and Demographic Characteristics
 Safety Analysis Set

	Non-Inhibitor	Prophylaxis (N=45)
Target Joints, n(%)		
Right Shoulder	1 (	2.2%)
Left Shoulder	1 (	2.2%)
Right Elbow	2 (	4.4%)
Left Elbow	7 (	15.6%)
Right Wrist	0 (	0.0%)
Left Wrist	0 (	0.0%)
Right Hip	2 (	4.4%)
Left Hip	0 (	0.0%)
Right Knee	4 (	8.9%)
Left Knee	8 (	17.8%)
Right Ankle	9 (	20.0%)
Left Ankle	7 (	15.6%)
Other	0 (	0.0%)
Hemophilic Arthropathy, n(%)		
Right Shoulder	3 (	6.7%)
Left Shoulder	2 (	4.4%)
Right Elbow	4 (	8.9%)
Left Elbow	7 (	15.6%)
Right Wrist	0 (	0.0%)
Left Wrist	0 (	0.0%)
Right Hip	0 (	0.0%)
Left Hip	0 (	0.0%)
Right Knee	10 (	22.2%)
Left Knee	5 (	11.1%)
Right Ankle	9 (	20.0%)
Left Ankle	7 (	15.6%)
Other	0 (	0.0%)
Geographical Region, n(%)		
Asia	15 (	33.3%)
Europe	17 (	37.8%)
Middle East	4 (	8.9%)
North America	9 (	20.0%)
Country, n(%)		
Canada	4 (	8.9%)
China	0 (	0.0%)
Croatia	1 (	2.2%)
France	0 (	0.0%)
Hong Kong	8 (	17.8%)
India	0 (	0.0%)
Italy	0 (	0.0%)
Japan	1 (	2.2%)
Korea	6 (	13.3%)
Mexico	4 (	8.9%)
Oman	4 (	8.9%)
Russia	0 (	0.0%)
Serbia	1 (	2.2%)
Spain	5 (	11.1%)
Taiwan	0 (	0.0%)
Turkey	10 (	22.2%)
United States	1 (	2.2%)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Disposition Events Summary
 Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58) n (%)
Disposition phase: Screening	
Participants Entered	58 (100.0%)
Discontinued	0 (0.0%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Pregnancy	0 (0.0%)
Protocol Deviation	0 (0.0%)
Screen failure	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	0 (0.0%)
Medication Error Without Associated Adverse Event	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Other	0 (0.0%)
Completed	58 (100.0%)
Ongoing	0 (0.0%)
Disposition phase: Treatment	
Participants Entered	58 (100.0%)
Discontinued	3 (5.2%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Pregnancy	0 (0.0%)
Protocol Deviation	0 (0.0%)
Screen failure	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	3 (5.2%)
Medication Error Without Associated Adverse Event	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Other	0 (0.0%)
Completed	0 (0.0%)
Ongoing	55 (94.8%)
Disposition Phase: Follow-up	
Participants Entered	3 (5.2%)
Discontinued	0 (0.0%)
Adverse Event	0 (0.0%)
Death	0 (0.0%)
Lack of Efficacy	0 (0.0%)
Lost to Follow-up	0 (0.0%)
Physician Decision	0 (0.0%)
Pregnancy	0 (0.0%)
Protocol Deviation	0 (0.0%)
Screen failure	0 (0.0%)
Study Terminated By Sponsor	0 (0.0%)
Withdrawal By Subject	0 (0.0%)
Medication Error Without Associated Adverse Event	0 (0.0%)
Withdrawal By Parent/Guardian	0 (0.0%)
Other	0 (0.0%)
Completed	2 (3.4%)
Ongoing	1 (1.7%)

N: Number of patients; n: Number of patients with non-missing status

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Baseline and Demographic Characteristics
 Safety Analysis Set

		Non-Inhibitor Prophylaxis (N=58)
Age (Years)		
Mean (SD)		31.24 (14.05)
Median		29.00
Min, Max		13.00, 61.00
Q1, Q3		18.00, 42.00
n (missing)		58 (0)
Age (Years), n(%)		
<18		12 (20.7%)
18-44		34 (58.6%)
45-64		12 (20.7%)
65-74		0 (0.0%)
>=75		0 (0.0%)
Sex, n(%)		
Male		58 (100.0%)
Race, n(%)		
Black or African American		0 (0.0%)
American Indian or Alaska Native		0 (0.0%)
Asian		26 (44.8%)
Native Hawaiian or Other Pacific Islander		0 (0.0%)
White		32 (55.2%)
Not Reported		0 (0.0%)
Ethnicity, n(%)		
Hispanic or Latino		9 (15.5%)
Not Hispanic or Latino		49 (84.5%)
Baseline eGFR* (mL/min/1.73m ²), n(%)		
missing		10 (17.2%)
>=90		35 (60.3%)
>= 60 to < 90		13 (22.4%)
>= 30 to < 60		0 (0.0%)
<30		0 (0.0%)
Weight (kg)		
Mean (SD)		72.15 (16.07)
Median		72.55
Min, Max		39.00, 128.80
Q1, Q3		60.80, 81.50
n (missing)		58 (0)
Height (cm)		
Mean (SD)		171.76 (7.49)
Median		172.90
Min, Max		149.00, 186.00
Q1, Q3		167.00, 177.40
n (missing)		57 (1)
Body Mass Index (kg/m ²)		
Mean (SD)		24.35 (4.64)
Median		23.99
Min, Max		15.96, 38.88
Q1, Q3		21.80, 27.11
n (missing)		57 (1)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Baseline and Demographic Characteristics
 Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)
Hemophilia Type, n(%)	
Hemophilia A	58 (100.0%)
Hemophilia B	0 (0.0%)
Age Groups, n(%)	
Adolescents (Ages 12 to < 18)	12 (20.7%)
Adults (Ages 18 to < 75)	46 (79.3%)
Age and Hemophilia Type, n(%)	
Adolescents Hem A	12 (20.7%)
Adolescents Hem B	0 (0.0%)
Adults Hem A	46 (79.3%)
Adults Hem B	0 (0.0%)
Family History of Hemophilia, n(%)	
Yes	31 (53.4%)
No	26 (44.8%)
Unknown	1 (1.7%)
Factor VIII Activity at Baseline, n(%)	
missing	1 (1.7%)
< 1%	53 (91.4%)
>= 1%	4 (6.9%)
Factor VIII Inhibitor at Baseline, n(%)	
Positive	0 (0.0%)
Negative	58 (100.0%)
ISTH Disease Severity, n(%)	
Mild	0 (0.0%)
Moderate	0 (0.0%)
Severe	58 (100.0%)
Number of Bleeds (in past 6 months)	
Mean (SD)	5.57 (9.86)
Median	2.00
Min, Max	0.00, 48.00
Q1, Q3	0.00, 5.00
n (missing)	58 (0)
Number of Bleeds (in past 6 months), n(%)	
Number of participants with >= 6 bleeds	14 (24.1%)
Number of participants with < 6 bleeds	44 (75.9%)
Number of Target Joints at Baseline, n(%)	
0	27 (46.6%)
1	12 (20.7%)
2	12 (20.7%)
>=3	7 (12.1%)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Baseline and Demographic Characteristics
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)

Target Joints, n(%)	
Right Shoulder	2 (3.4%)
Left Shoulder	1 (1.7%)
Right Elbow	6 (10.3%)
Left Elbow	11 (19.0%)
Right Wrist	0 (0.0%)
Left Wrist	0 (0.0%)
Right Hip	3 (5.2%)
Left Hip	2 (3.4%)
Right Knee	6 (10.3%)
Left Knee	13 (22.4%)
Right Ankle	12 (20.7%)
Left Ankle	10 (17.2%)
Other	0 (0.0%)
Hemophilic Arthropathy, n(%)	
Right Shoulder	4 (6.9%)
Left Shoulder	2 (3.4%)
Right Elbow	9 (15.5%)
Left Elbow	12 (20.7%)
Right Wrist	0 (0.0%)
Left Wrist	0 (0.0%)
Right Hip	1 (1.7%)
Left Hip	1 (1.7%)
Right Knee	13 (22.4%)
Left Knee	10 (17.2%)
Right Ankle	12 (20.7%)
Left Ankle	9 (15.5%)
Other	0 (0.0%)
Geographical Region, n(%)	
Asia	20 (34.5%)
Europe	18 (31.0%)
Middle East	10 (17.2%)
North America	10 (17.2%)
Country, n(%)	
Canada	5 (8.6%)
China	3 (5.2%)
Croatia	1 (1.7%)
France	0 (0.0%)
Hong Kong	9 (15.5%)
India	0 (0.0%)
Italy	1 (1.7%)
Japan	1 (1.7%)
Korea	7 (12.1%)
Mexico	4 (6.9%)
Oman	10 (17.2%)
Russia	0 (0.0%)
Serbia	1 (1.7%)
Spain	5 (8.6%)
Taiwan	0 (0.0%)
Turkey	10 (17.2%)
United States	1 (1.7%)

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Treatment duration (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	368.53 (143.955)
Median	351.50
Q1, Q3	251.00, 483.00
Min, Max	147.0, 693.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as the last dose date - the first dose date + 7.

Anhang 4-G2.2: Blutungsereignisse

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for total bleeds (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Completion Rates for Annualized Bleeding Rate for total bleeds
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Analysis of Annualized Bleeding Rate for total bleeds
 Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)		
Number (%) of patients without any bleeds	18 (31.0)		
Number of bleeds			
Number	180		
Mean (SD)	3.10 (4.778)		
Median	1.0		
Q1, Q3	0.0 4.0		
Min, Max	0 26		
Annualized bleeding rate (ABR)			
Mean (SD)	3.47 (6.485)		
Median	1.45		
Q1, Q3	0.00 4.31		
Min, Max	0.00 39.76		
Model derived ABR [1]			
Estimate (95% CI)	3.37 (2.30, 4.92)		
CSR			
Model derived ABR [2]			
Estimate (95% CI)	3.37 (1.85, 4.88)		

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for treated bleeds (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized Bleeding Rate for treated bleeds
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Analysis of Annualized Bleeding Rate for treated bleeds
 Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)
Number (%) of patients without any bleeds	20 (34.5)
Number of bleeds	
Number	155
Mean (SD)	2.67 (3.818)
Median	1.0
Q1, Q3	0.0 4.0
Min, Max	0 16
Annualized bleeding rate (ABR)	
Mean (SD)	3.03 (5.891)
Median	1.19
Q1, Q3	0.00 3.59
Min, Max	0.00 39.76
Model derived ABR [1]	
Estimate (95% CI)	2.92 (1.98, 4.30)
CSR	
Model derived ABR [2]	
Estimate (95% CI)	2.92 (1.60, 4.24)

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for untreated bleeds (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Completion Rates for Annualized Bleeding Rate for untreated bleeds
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized Bleeding Rate for untreated bleeds
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)		
Number (%) of patients without any bleeds	48 (82.8)		
Number of bleeds			
Number	25		
Mean (SD)	0.43 (1.992)		
Median	0.0		
Q1, Q3	0.0 0.0		
Min, Max	0 15		
Annualized bleeding rate (ABR)			
Mean (SD)	0.43 (1.953)		
Median	0.00		
Q1, Q3	0.00 0.00		
Min, Max	0.00 14.65		
Model derived ABR [1]			
Estimate (95% CI)	0.44 (0.19, 1.03)		
CSR			
Model derived ABR [2]			
Estimate (95% CI)	0.44 (-0.07, 0.95)		

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Spontaneous (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final Marstacimab Hemophilia A Datacut: B7841007 (09OCT2023) Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Spontaneous Safety Analysis Set	
	Non-Inhibitor Prophylaxis (N=58) n (%)
	58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized Bleeding Rate for specific type of total bleeds: Spontaneous
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)		
Number (%) of patients without any bleeds	30 (51.7)		
Number of bleeds			
Number	125		
Mean (SD)	2.16 (4.234)		
Median	0.0		
Q1, Q3	0.0 2.0		
Min, Max	0 23		
Annualized bleeding rate (ABR)			
Mean (SD)	2.49 (6.312)		
Median	0.00		
Q1, Q3	0.00 1.76		
Min, Max	0.00 39.76		
Model derived ABR [1]			
Estimate (95% CI)	2.42 (1.44, 4.07)		
CSR			
Model derived ABR [2]			
Estimate (95% CI)	2.42 (0.93, 3.91)		

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Traumatic (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Traumatic
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized Bleeding Rate for specific type of total bleeds: Traumatic
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)		
Number (%) of patients without any bleeds	32 (55.2)		
Number of bleeds			
Number	55		
Mean (SD)	0.95 (1.407)		
Median	0.0		
Q1, Q3	0.0 1.0		
Min, Max	0 6		
Annualized bleeding rate (ABR)			
Mean (SD)	0.97 (1.565)		
Median	0.00		
Q1, Q3	0.00 1.41		
Min, Max	0.00 6.96		
Model derived ABR [1]			
Estimate (95% CI)	0.95 (0.65, 1.41)		
CSR			
Model derived ABR [2]			
Estimate (95% CI)	0.95 (0.60, 1.31)		

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Joint (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Joint
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Analysis of Annualized Bleeding Rate for specific type of total bleeds: Joint
 Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)
Number (%) of patients without any bleeds	23 (39.7)
Number of bleeds	
Number	145
Mean (SD)	2.50 (3.822)
Median	1.0
Q1, Q3	0.0 3.0
Min, Max	0 16
Annualized bleeding rate (ABR)	
Mean (SD)	2.83 (5.968)
Median	0.95
Q1, Q3	0.00 3.59
Min, Max	0.00 39.76
Model derived ABR [1]	
Estimate (95% CI)	2.74 (1.79, 4.18)
CSR	
Model derived ABR [2]	
Estimate (95% CI)	2.74 (1.38, 4.09)

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized Bleeding Rate for specific type of total bleeds: Soft tissue/muscle/other
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)		
Number (%) of patients without any bleeds	39 (67.2)		
Number of bleeds			
Number	36		
Mean (SD)	0.62 (1.775)		
Median	0.0		
Q1, Q3	0.0 1.0		
Min, Max	0 13		
Annualized bleeding rate (ABR)			
Mean (SD)	0.65 (1.785)		
Median	0.00		
Q1, Q3	0.00 0.73		
Min, Max	0.00 12.70		
Model derived ABR [1]			
Estimate (95% CI)	0.64 (0.38, 1.10)		
CSR			
Model derived ABR [2]			
Estimate (95% CI)	0.64 (0.18, 1.11)		

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Bleeding Rate for specific type of total bleeds: Target joint (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized Bleeding Rate for specific type of total bleeds: Target joint
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized Bleeding Rate for specific type of total bleeds: Target joint
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)		
Number (%) of patients without any bleeds	43 (74.1)		
Number of bleeds			
Number	72		
Mean (SD)	1.24 (3.080)		
Median	0.0		
Q1, Q3	0.0 1.0		
Min, Max	0 16		
Annualized bleeding rate (ABR)			
Mean (SD)	1.53 (5.474)		
Median	0.00		
Q1, Q3	0.00 0.93		
Min, Max	0.00 39.76		
Model derived ABR [1]			
Estimate (95% CI)	1.48 (0.67, 3.28)		
CSR			
Model derived ABR [2]			
Estimate (95% CI)	1.48 (0.19, 2.77)		

CI: Confidence Interval; Min: Minimum; Max: Maximum; N: Number of patients; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

[2] Based on a repeated measures generalized linear model (GLM) with negative binomial distribution and identity link function.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of patients without any bleeds (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	366.40 (143.219)
Median	349.00
Q1, Q3	246.00, 477.00
Min, Max	147.0, 690.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for patients without any bleeds
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of patients without any bleeds
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

Number (%) of patients without any bleeds

18 (31.0)

N: Number of patients

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of patients with 0 Target Joints (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	362.66 (143.859)
Median	345.50
Q1, Q3	245.00, 477.00
Min, Max	141.0, 687.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for patients with 0 Target Joints
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Analysis of patients with 0 Target Joints
 Safety Analysis Set

Non-Inhibitor Prophylaxis
 (N=58)

Number (%) of patients with 0 target joints

50 (86.2)

N: Number of patients
 ,

Anhang 4-G2.3: Faktor-Ersatztherapie

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized Infusion Rate (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	362.53 (143.955)
Median	345.50
Q1, Q3	245.00, 477.00
Min, Max	141.0, 687.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized Infusion Rate
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized Infusion Rate
Safety Analysis Set

	Non-Inhibitor Prophylaxis (N=58)
Number (%) of patients without any infusions	18 (31.0)
Number of infusions Mean (SD)	4.69 (6.441)
Annualized infusion rate (AIR) Mean (SD)	5.10 (8.036)
Model derived AIR [1] Estimate (95% CI)	5.02 (3.40, 7.41)

CI: Confidence Interval; N: Number of patients; SD: Standard Deviation

CSR: same model as for Annualized Bleeding Rate (ABR)

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized On-Demand Infusion Rate (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	362.53 (143.955)
Median	345.50
Q1, Q3	245.00, 477.00
Min, Max	141.0, 687.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized On-Demand Infusion Rate
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized On-Demand Infusion Rate
Safety Analysis Set

		Non-Inhibitor Prophylaxis (N=58)
Number (%) of patients without any infusions		18 (31.0)
Number of infusions Mean (SD)		4.69 (6.441)
Annualized infusion rate (AIR) Mean (SD)		5.10 (8.036)
Model derived AIR [1] Estimate (95% CI)		5.02 (3.40, 7.41)

CI: Confidence Interval; N: Number of patients; SD: Standard Deviation

CSR: same model as for Annualized Bleeding Rate (ABR)

[1] Based on a generalized linear model (GLM) with negative binomial distribution, log link function and log number of days follow up as the patient offset variable.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Follow-up duration of Annualized On-Demand FVIII-Consumption (IU/kg) (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	362.53 (143.955)
Median	345.50
Q1, Q3	245.00, 477.00
Min, Max	141.0, 687.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as last dose date - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Completion Rates for Annualized On-Demand FVIII-Consumption (IU/kg)
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n (%)

58 (100.0)

N: Number of patients; n: Number of patients with non-missing values

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Analysis of Annualized On-Demand FVIII-Consumption (IU/kg)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

Annualized On-Demand FVIII-Consumption
Mean (SD)

118.13 (229.224)

N: Number of patients

Anhang 4-G2.4: Gesundheitszustand

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Follow-up duration of EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS) - Follow-up duration (Days)
Safety Analysis Set

		Non-Inhibitor Prophylaxis (N=45)
n (missing)		45 (0)
Mean (SD)		125.91 (128.330)
Median		176.00
Q1, Q3		1.00, 190.00
Min, Max		1.0, 379.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement - the first dose date.

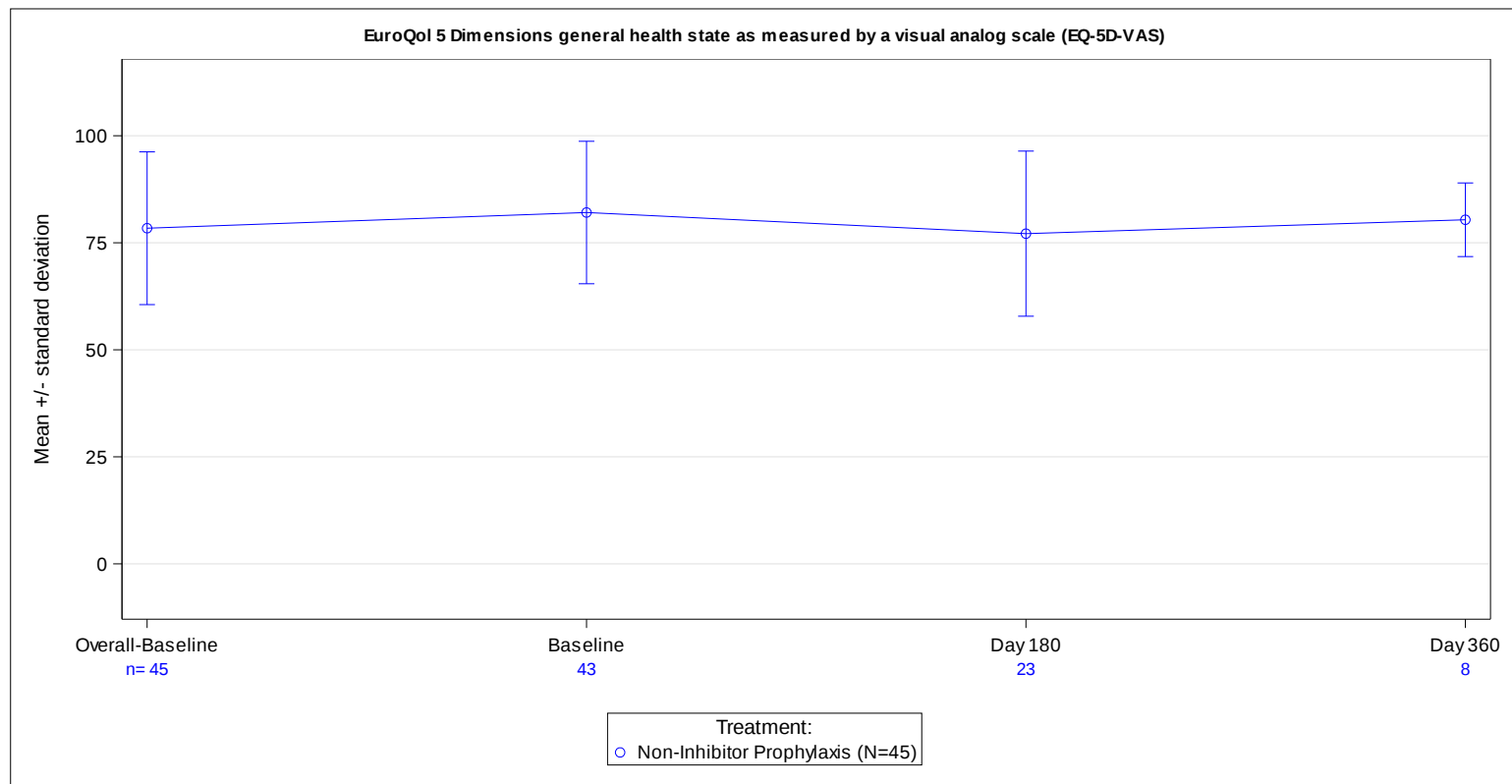
Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Completion Rates for EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
Safety Analysis Set

Visit	Non-Inhibitor Prophylaxis (N=45) n (%)
Overall-Baseline	45 (100.0)
Baseline	43 (95.6)
Day 180	23 (51.1)
Day 360	8 (17.8)

N: Number of patients; n: Number of patients with non-missing values

Overall-Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Graphical Summary of EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
Safety Analysis Set



N: Number of patients; n: Number of patients with non-missing values

Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Descriptive Statistics of EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
Safety Analysis Set

Visit	Baseline type	Non-Inhibitor Prophylaxis (N=45)					
		Value at Baseline		Value at Visit		Change from Baseline	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Overall Baseline	Overall Baseline	45	78.40 (17.84)	45	78.40 (17.84)		
Baseline	Overall Baseline	45	78.40 (17.84)	43	82.07 (16.64)	43	3.81 (8.17)
	Baseline	43	82.07 (16.64)	43	82.07 (16.64)		
Day 180	Overall Baseline	45	78.40 (17.84)	23	77.13 (19.29)	23	3.43 (15.50)
	Baseline	43	82.07 (16.64)	23	77.13 (19.29)	23	-1.26 (12.91)
Day 360	Overall Baseline	45	78.40 (17.84)	8	80.38 (8.60)	8	6.75 (10.36)
	Baseline	43	82.07 (16.64)	8	80.38 (8.60)	8	-1.88 (4.05)

N: Number of patients; n: Number of patients with non-missing values; SD: Standard Deviation
Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in EuroQol 5 Dimensions general health state as measured by a visual analog scale (EQ-5D-VAS)
Safety Analysis Set

Visit	Change from		Non-Inhibitor Prophylaxis (N=45)
Baseline	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	3 / 45 (6.7)
Day 180	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	5 / 45 (11.1)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	2 / 43 (4.7)
Day 360	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	1 / 45 (2.2)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	0 / 43 (0.0)

N: Number of patients
Only observed values are included.
Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Anhang 4-G2.5: Körperliche Funktionsfähigkeit

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: E7841007 (10MAR2023)
Follow-up duration of Hemophilia Joint Health Score (HJHS) Total Score - Follow-up duration (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=45)

n (missing)	45 (0)
Mean (SD)	115.40 (124.709)
Median	175.00
Q1, Q3	1.00, 183.00
Min, Max	1.0, 366.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement - the first dose date.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

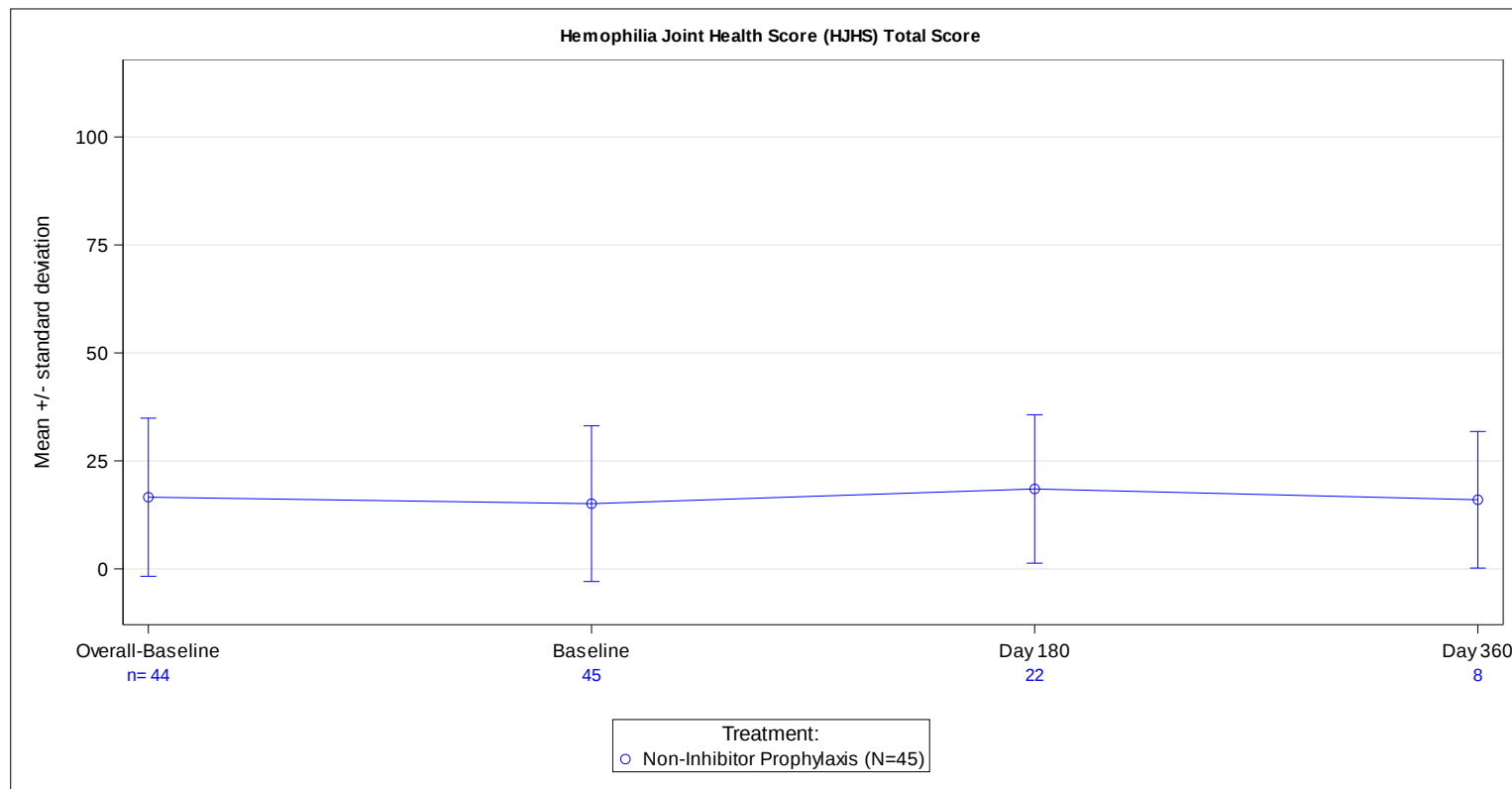
Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Completion Rates for Hemophilia Joint Health Score (HJHS) Total Score
Safety Analysis Set

Visit	Non-Inhibitor Prophylaxis (N=45) n (%)
Overall-Baseline	44 (97.8)
Baseline	45 (100.0)
Day 180	22 (48.9)
Day 360	8 (17.8)

N: Number of patients; n: Number of patients with non-missing values

Overall-Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Graphical Summary of Hemophilia Joint Health Score (HJHS) Total Score
Safety Analysis Set



N: Number of patients; n: Number of patients with non-missing values
Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (10MAR2023)
 Descriptive Statistics of Hemophilia Joint Health Score (HJHS) Total Score
 Safety Analysis Set

Visit	Baseline type	Non-Inhibitor Prophylaxis (N=45)					
		Value at Baseline		Value at Visit		Change from Baseline	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Overall Baseline	Overall Baseline	44	16.60 (18.31)	44	16.60 (18.31)		
Baseline	Overall Baseline	44	16.60 (18.31)	45	15.09 (18.03)	44	-1.16 (5.59)
	Baseline	45	15.09 (18.03)	45	15.09 (18.03)		
Day 180	Overall Baseline	44	16.60 (18.31)	22	18.51 (17.18)	22	-2.49 (15.71)
	Baseline	45	15.09 (18.03)	22	18.51 (17.18)	22	-2.93 (14.94)
Day 360	Overall Baseline	44	16.60 (18.31)	8	16.00 (15.81)	8	-3.05 (9.15)
	Baseline	45	15.09 (18.03)	8	16.00 (15.81)	8	0.70 (1.88)

N: Number of patients; n: Number of patients with non-missing values; SD: Standard Deviation
 Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Analysis of patients with ≥ 19 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Joint Health Score (HJHS) Total Score
Safety Analysis Set

Visit	Change from		Non-Inhibitor Prophylaxis (N=45)
Baseline	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	1 / 44 (2.3)
Day 180	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	1 / 44 (2.3)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	1 / 45 (2.2)
Day 360	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	1 / 44 (2.3)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	0 / 45 (0.0)

N: Number of patients
Only observed values are included.
Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Anhang 4-G2.6: Gesundheitsbezogene Lebensqualität

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Follow-up duration of Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score - Follow-up duration (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=36)

n (missing)	36 (0)
Mean (SD)	117.11 (132.093)
Median	44.00
Q1, Q3	1.00, 193.50
Min, Max	1.0, 366.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement - the first dose date.
Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

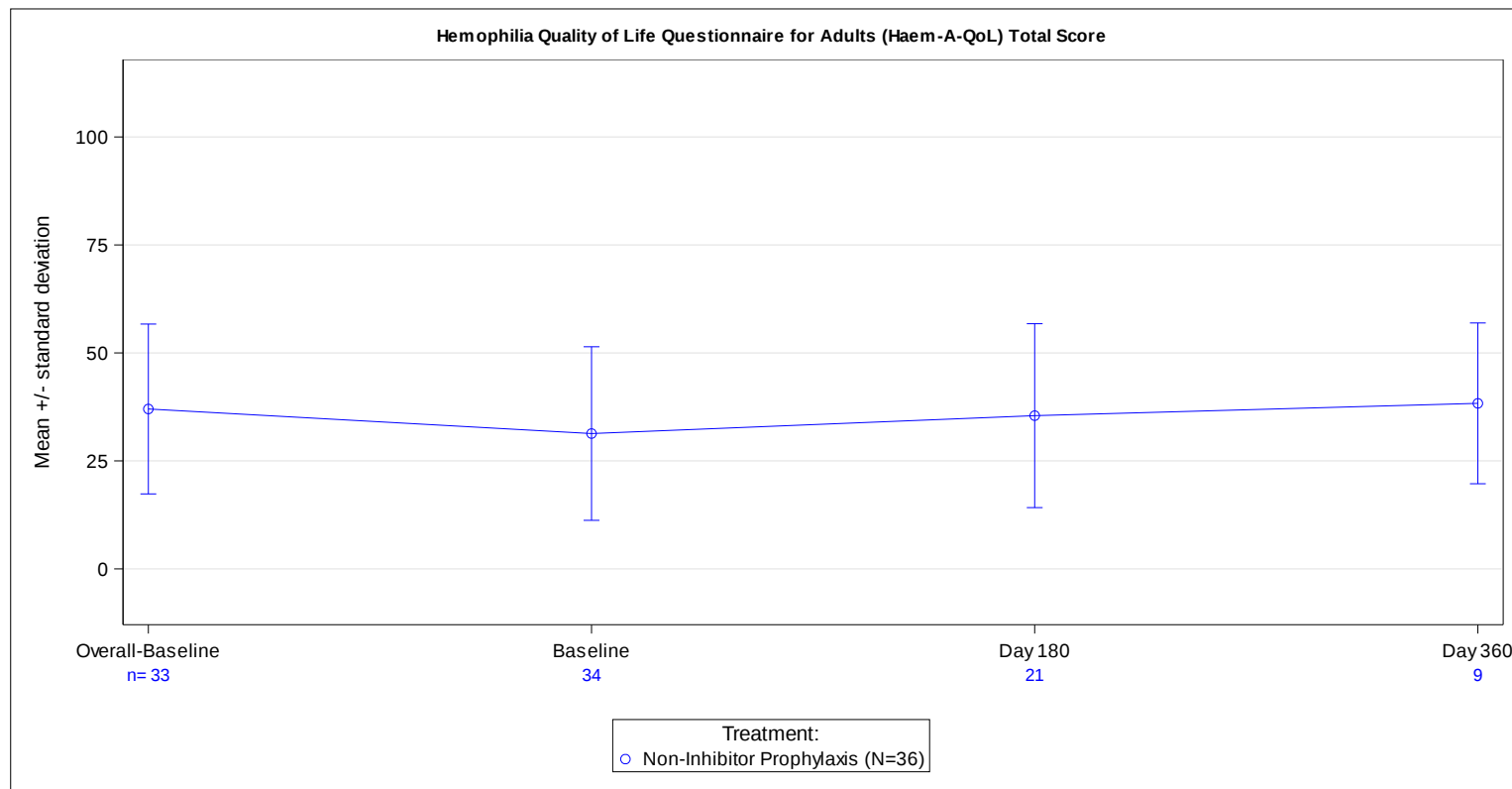
Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Completion Rates for Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
Safety Analysis Set

Visit	Non-Inhibitor Prophylaxis (N=36) n (%)
Overall-Baseline	33 (91.7)
Baseline	34 (94.4)
Day 180	21 (58.3)
Day 360	9 (25.0)

N: Number of patients; n: Number of patients with non-missing values

Overall-Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.
Assessed for participants 17 to < 75 years of age.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Graphical Summary of Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
Safety Analysis Set



N: Number of patients; n: Number of patients with non-missing values

Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Descriptive Statistics of Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
Safety Analysis Set

Visit	Baseline type	Non-Inhibitor Prophylaxis (N=36)					
		Value at Baseline		Value at Visit		Change from Baseline	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Overall Baseline	Overall Baseline	33	37.02 (19.66)	33	37.02 (19.66)		
Baseline	Overall Baseline	33	37.02 (19.66)	34	31.33 (20.09)	31	-6.01 (10.06)
	Baseline	34	31.33 (20.09)	34	31.33 (20.09)		
Day 180	Overall Baseline	33	37.02 (19.66)	21	35.47 (21.29)	20	-3.74 (12.84)
	Baseline	34	31.33 (20.09)	21	35.47 (21.29)	21	1.72 (9.04)
Day 360	Overall Baseline	33	37.02 (19.66)	9	38.32 (18.62)	8	-4.17 (8.04)
	Baseline	34	31.33 (20.09)	9	38.32 (18.62)	9	0.55 (6.22)

N: Number of patients; n: Number of patients with non-missing values; SD: Standard Deviation
Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) Total Score
Safety Analysis Set

Visit	Change from		Non-Inhibitor Prophylaxis (N=36)
Baseline	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	6 / 33 (18.2)
Day 180	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	4 / 33 (12.1)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	0 / 34 (0.0)
Day 360	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	1 / 33 (3.0)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	0 / 34 (0.0)

N: Number of patients
Only observed values are included.
Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.
Assessed for participants 17 to < 75 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Follow-up duration of Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score - Follow-up duration (Days)
Safety Analysis Set

		Non-Inhibitor Prophylaxis (N=9)
n (missing)	9 (0)	
Mean (SD)	42.11 (81.602)	
Median	1.00	
Q1, Q3	1.00, 1.00	
Min, Max	1.0, 190.0	

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as date of last measurement - the first dose date.
Assessed for participants 12 to < 17 years of age.

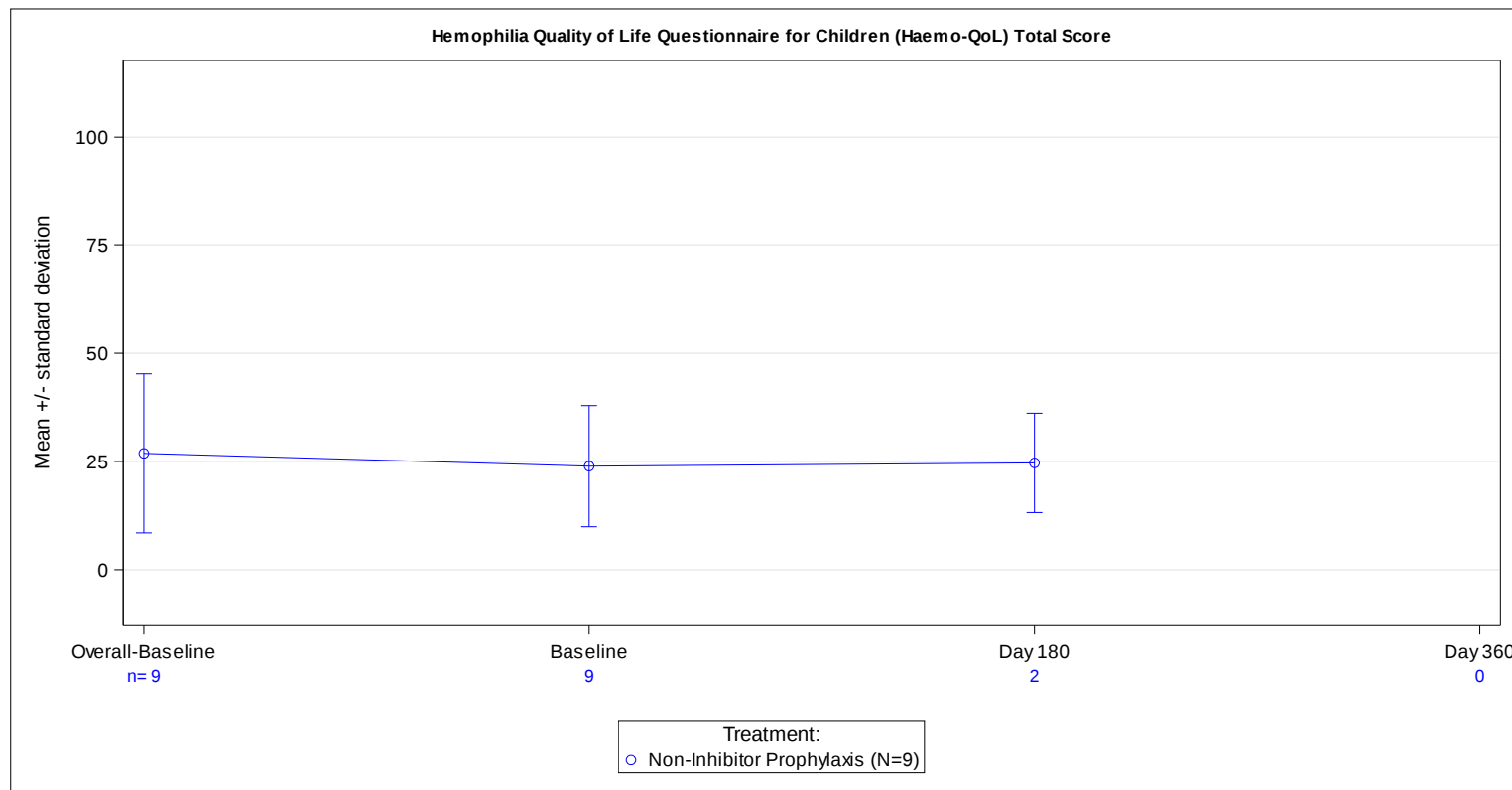
Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Completion Rates for Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
Safety Analysis Set

Visit	Non-Inhibitor Prophylaxis (N=9) n (%)
Overall-Baseline	9 (100.0)
Baseline	9 (100.0)
Day 180	2 (22.2)
Day 360	0 (0.0)

N: Number of patients; n: Number of patients with non-missing values

Overall-Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.
Assessed for participants 12 to < 17 years of age.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Graphical Summary of Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
Safety Analysis Set



N: Number of patients; n: Number of patients with non-missing values

Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Assessed for participants 12 to < 17 years of age.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Descriptive Statistics of Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
Safety Analysis Set

Visit	Baseline type	Non-Inhibitor Prophylaxis (N=9)					
		Value at Baseline		Value at Visit		Change from Baseline	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Overall Baseline	Overall Baseline	9	26.88 (18.38)	9	26.88 (18.38)		
Baseline	Overall Baseline	9	26.88 (18.38)	9	23.92 (14.00)	9	-2.96 (7.65)
	Baseline	9	23.92 (14.00)	9	23.92 (14.00)		
Day 180	Overall Baseline	9	26.88 (18.38)	2	24.68 (11.48)	2	-2.76 (13.55)
	Baseline	9	23.92 (14.00)	2	24.68 (11.48)	2	-5.52 (3.67)
Day 360	Overall Baseline	9	26.88 (18.38)	0	NE (NE)	0	NE (NE)
	Baseline	9	23.92 (14.00)	0	NE (NE)	0	NE (NE)

N: Number of patients; n: Number of patients with non-missing values; SD: Standard Deviation
Only observed values are included.

Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (10MAR2023)
Analysis of patients with ≥ 15 points Improvement from baseline (Improvement $\geq 15\%$ of the total scale) in Hemophilia Quality of Life Questionnaire for Children (Haemo-QoL) Total Score
Safety Analysis Set

Visit	Change from		Non-Inhibitor Prophylaxis (N=9)	
Baseline	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	1 / 9	(11.1)
Day 180	Overall Baseline	Number of patients with improvement from overall baseline / Number of patients with overall baseline value (%)	0 / 9	(0.0)
	Baseline	Number of patients with improvement from baseline / Number of patients with baseline value (%)	0 / 9	(0.0)

N: Number of patients
Only observed values are included.
Overall Baseline: pre-dose measurement on Day 1 of Active Treatment Phase in Study B7841005. Baseline: The last pre-dose measurement in Study B7841007. If missing then B7841005 visit 20 data are used.
Assessed for participants 12 to < 17 years of age.

Anhang 4-G2.7: Verträglichkeit

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Safety Follow-up duration (Days)
Safety Analysis Set

Non-Inhibitor Prophylaxis
(N=58)

n (missing)	58 (0)
Mean (SD)	389.53 (143.955)
Median	372.50
Q1, Q3	272.00, 504.00
Min, Max	168.0, 714.0

Min: Minimum; Max: Maximum; N: Number of patients; n: Number of patients with non-missing values; Q1: 25%-Quartile; Q3: 75%-Quartile; SD: Standard Deviation
Follow-up duration defined as treatment duration + 21.

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of AE
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

35/ 58 (60.3)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of AE excluding PTs related to underlying disease progression
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

34/ 58 (58.6)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious AE
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

4/ 58 (6.9)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious AE excluding PTs related to underlying disease progression
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

3/ 58 (5.2)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe AE
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

3/ 58 (5.2)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe AE excluding PTs related to underlying disease progression
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

2/ 58 (3.4)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Non-severe AE (Mild, Moderate)
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

32/ 58 (55.2)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Non-severe AE (Mild, Moderate) excluding PTs related to underlying disease progression
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

32/ 58 (55.2)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of AE leading to discontinuation of study drug
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of AE leading to discontinuation of study drug excluding PTs related to underlying disease progression
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final Marstacimab Hemophilia A Datacut: B7841007 (09OCT2023) Overall Summary of AE leading to discontinuation of study Safety Analysis Set	
	Non-Inhibitor Prophylaxis (N=58) n/N (%)
	0/ 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of AE leading to discontinuation of study excluding PTs related to underlying disease progression
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of AE leading to death
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of AE leading to death excluding PTs related to underlying disease progression
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of COVID-19
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

3/ 58 (5.2)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious COVID-19
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe COVID-19
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Cardiac arrhythmias
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of Serious Cardiac arrhythmias
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe Cardiac arrhythmias
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Embolic and thrombotic events (SMQ)
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58) n/N (%)
0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious Embolic and thrombotic events (SMQ)
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58) n/N (%)
0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final Marstacimab Hemophilia A Datacut: B7841007 (09OCT2023) Overall Summary of Severe Embolic and thrombotic events (SMQ) Safety Analysis Set	
	Non-Inhibitor Prophylaxis (N=58) n/N (%)
	0/ 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Gastrointestinal varices/Haemorrhoids
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58) n/N (%)
0/ 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of Serious Gastrointestinal varices/Haemorrhoids
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe Gastrointestinal varices/Haemorrhoids
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Haemodynamic oedema, effusions and fluid overload
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of Serious Haemodynamic oedema, effusions and fluid overload
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final Marstacimab Hemophilia A Datacut: B7841007 (09OCT2023) Overall Summary of Severe Haemodynamic oedema, effusions and fluid overload Safety Analysis Set	
	Non-Inhibitor Prophylaxis (N=58) n/N (%)
	0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Haemorrhages
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious Haemorrhages
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe Haemorrhages
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Hepatic disorders
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious Hepatic disorders
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe Hepatic disorders
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Hypersensitivity
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious Hypersensitivity
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
 Marstacimab
 Hemophilia A
 Datacut: B7841007 (09OCT2023)
 Overall Summary of Severe Hypersensitivity
 Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
 n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
 N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Hypertension
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

2/ 58 (3.4)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Serious Hypertension
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Severe Hypertension
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

0 / 58 (0.0)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of Injection site reactions
Safety Analysis Set

Non-Inhibitor Prophylaxis (N=58)
n/N (%)

6/ 58 (10.3)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final Marstacimab Hemophilia A Datacut: B7841007 (09OCT2023) Overall Summary of Serious Injection site reactions Safety Analysis Set	
	Non-Inhibitor Prophylaxis (N=58) n/N (%)
	0/ 58 (0.0)

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Pfizer Inc.: Final Marstacimab Hemophilia A Datacut: B7841007 (09OCT2023) Overall Summary of Severe Injection site reactions Safety Analysis Set	
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N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Incidence of AE leading to discontinuation of study drug by SOC, PT
Safety Analysis Set

!!! There are no Observations for this Report !!!

MedDRA v26.0 coding dictionary applied.
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Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Incidence of AE leading to discontinuation of study by SOC, PT
Safety Analysis Set

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MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of frequent AE by SOC, PT (incidence $\geq 10\%$ or ≥ 10 patients)
Safety Analysis Set

System organ class (SOC) / Preferred term (PT)	Non-Inhibitor Prophylaxis (N=58) n/N (%)
SOC: General disorders and administration site conditions	8/ 58 (13.8)
SOC: Infections and infestations	15/ 58 (25.9)
SOC: Musculoskeletal and connective tissue disorders	6/ 58 (10.3)

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of frequent Serious AE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

!!! There are no Observations for this Report !!!

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event

Pfizer Inc.: Final
Marstacimab
Hemophilia A
Datacut: B7841007 (09OCT2023)
Overall Summary of frequent Severe AE (NCI CTCAE grade ≥ 3) by SOC, PT (incidence $\geq 5\%$ or ≥ 10 patients)
Safety Analysis Set

!!! There are no Observations for this Report !!!

MedDRA v26.0 coding dictionary applied.
N: Number of patients; n: Number of patients with event