

**Dossier zur Nutzenbewertung
gemäß § 35a SGB V**

Atogepant (AQUIPTA®)

AbbVie Deutschland GmbH & Co. KG

Separater Anhang 4-G: Ergänzende Unterlagen

*Erwachsene mit Migräne mit oder ohne Aura, die einer
Akutbehandlung bedürfen*

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Ergänzende Unterlagen zur Studie M24-305 (ECLIPSE)

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TABLE 4.1.1

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

SUBJECT DISPOSITION

SAF1 ANALYSIS SET

	Treatment Sequence 1 (N=623)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=202)	Treatment Sequence 4 (N=208)	Total (N=1232)
Total Randomized - n (%)	623 (100)	199 (100)	202 (100)	208 (100)	1232 (100)
Never Received any Study Drug - n (%)	0	0	0	0	0
Treated Study Drug - n (%)	623 (100)	199 (100)	202 (100)	208 (100)	1232 (100)
Completed DB Treatment Period - n (%)	526 (84.4)	170 (85.4)	176 (87.1)	173 (83.2)	1045 (84.8)
With 4 Qualifying Attacks - n (%)	522 (83.8)	167 (83.9)	175 (86.6)	173 (83.2)	1037 (84.2)
Without 4 Qualifying Attacks, but Entered the OL Period [1] - n (%)	4 (0.6)	3 (1.5)	1 (0.5)	0	8 (0.6)
Discontinued Study - DB Period - n (%)	97 (15.6)	29 (14.6)	26 (12.9)	35 (16.8)	187 (15.2)
Primary Reason for Study Discontinuation					
Death - n (%)	0	0	0	0	0
Lost to Follow-Up - n (%)	1 (0.2)	1 (0.5)	0	0	2 (0.2)
Withdrawal by Subject - n (%)	24 (3.9)	4 (2.0)	4 (2.0)	5 (2.4)	37 (3.0)
Withdrawal by Subject - Adverse Event - n (%)	0	0	0	0	0
Study Terminated by Sponsor - n (%)	0	0	0	0	0
Logistical problem [geo-political restrictions] - n (%)	0	0	0	0	0
Subject Did Not Treat 4 Qualifying Attacks during DB Period - n (%)	68 (10.9)	22 (11.1)	21 (10.4)	29 (13.9)	140 (11.4)
Other - n (%)	4 (0.6)	2 (1.0)	1 (0.5)	1 (0.5)	8 (0.6)

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

[1] Subjects who completed DB period without 4 qualifying attacks but entered the OL period refer to those subjects who received DB doses but did not experience 4 qualifying attacks, and either received OL doses or were ongoing in the OL period without discontinuing from the study.

DB=Double blind, n=Number of subjects within a specific category, N=Number of subjects within the population, OL=Open label, SAF1=Safety analysis set of the DB phase

Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 SUBJECT DISPOSITION
 SAF1 ANALYSIS SET

	Treatment Sequence 1 (N=623)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=202)	Treatment Sequence 4 (N=208)	Total (N=1232)
Discontinued Study Treatment - DB Period - n (%)	97 (15.6)	29 (14.6)	26 (12.9)	35 (16.8)	187 (15.2)
Primary Reason for Study Treatment Discontinuation					
Adverse Event - n (%)	5 (0.8)	0	0	2 (1.0)	7 (0.6)
Lost to Follow-Up - n (%)	1 (0.2)	1 (0.5)	0	0	2 (0.2)
Lack of Efficacy - n (%)	2 (0.3)	0	0	0	2 (0.2)
Withdrawal by Subject - n (%)	18 (2.9)	5 (2.5)	4 (2.0)	3 (1.4)	30 (2.4)
Study Terminated by Sponsor - n (%)	0	0	0	0	0
Logistical problem [geo-political restrictions] - n (%)	0	0	0	0	0
Subject Did Not Treat 4 Qualifying Attacks during DB Period - n (%)	68 (10.9)	22 (11.1)	21 (10.4)	29 (13.9)	140 (11.4)
Other - n (%)	3 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	6 (0.5)

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

[1] Subjects who completed DB period without 4 qualifying attacks but entered the OL period refer to those subjects who received DB doses but did not experience 4 qualifying attacks, and either received OL doses or were ongoing in the OL period without discontinuing from the study.

DB=Double blind, n=Number of subjects within a specific category, N=Number of subjects within the population, OL=Open label, SAF1=Safety analysis set of the DB phase

Percentages are calculated as $100 \times (n/N)$.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DEMOGRAPHIC CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Sex - n (%)					
Male	88 (14.2)	29 (14.6)	35 (17.6)	30 (14.5)	182 (14.9)
Female	530 (85.8)	170 (85.4)	164 (82.4)	177 (85.5)	1041 (85.1)
Missing	0	0	0	0	0
Age (years)					
n (missing)	618 (0)	199 (0)	199 (0)	207 (0)	1223 (0)
Mean (SD)	41.29 (11.40)	41.95 (10.89)	41.85 (11.37)	40.58 (11.69)	41.37 (11.36)
Median	42.00	42.00	43.00	41.00	42.00
Min, Max	18, 74	19, 68	19, 68	19, 68	18, 74
Age Group (years) - n (%)					
< 20	9 (1.5)	2 (1.0)	3 (1.5)	3 (1.4)	17 (1.4)
20 - 29	99 (16.0)	24 (12.1)	34 (17.1)	36 (17.4)	193 (15.8)
30 - 39	158 (25.6)	58 (29.1)	39 (19.6)	54 (26.1)	309 (25.3)
40 - 49	200 (32.4)	66 (33.2)	70 (35.2)	69 (33.3)	405 (33.1)
50 - 59	116 (18.8)	34 (17.1)	43 (21.6)	34 (16.4)	227 (18.6)
60 - 69	30 (4.9)	15 (7.5)	10 (5.0)	11 (5.3)	66 (5.4)
>= 70	6 (1.0)	0	0	0	6 (0.5)
Missing	0	0	0	0	0
< 40	266 (43.0)	84 (42.2)	76 (38.2)	93 (44.9)	519 (42.4)
40 - 64	337 (54.5)	113 (56.8)	122 (61.3)	108 (52.2)	680 (55.6)
>= 65	15 (2.4)	2 (1.0)	1 (0.5)	6 (2.9)	24 (2.0)
Missing	0	0	0	0	0

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] Black or African American, American Indian, Alaska Native, Native Hawaiian or Other Pacific Islander.

[2] When more than one race is selected, Race = Multiple. A subject is counted at most once.

DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DEMOGRAPHIC CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Race - n (%)					
White	366 (59.2)	119 (59.8)	119 (59.8)	123 (59.4)	727 (59.4)
Asian	243 (39.3)	78 (39.2)	79 (39.7)	83 (40.1)	483 (39.5)
Other [1]	5 (0.8)	0	0	1 (0.5)	6 (0.5)
Multiple [2]	4 (0.6)	2 (1.0)	1 (0.5)	0	7 (0.6)
Missing	0	0	0	0	0
Ethnicity - n (%)					
Hispanic or Latino	18 (2.9)	6 (3.0)	4 (2.0)	9 (4.3)	37 (3.0)
Not Hispanic or Latino	600 (97.1)	193 (97.0)	195 (98.0)	198 (95.7)	1186 (97.0)
Missing	0	0	0	0	0
Region - n (%)					
Europe	376 (60.8)	119 (59.8)	119 (59.8)	124 (59.9)	738 (60.3)
Germany	24 (3.9)	8 (4.0)	9 (4.5)	12 (5.8)	53 (4.3)
China	114 (18.4)	38 (19.1)	40 (20.1)	35 (16.9)	227 (18.6)
Japan	70 (11.3)	25 (12.6)	23 (11.6)	27 (13.0)	145 (11.9)
Other	58 (9.4)	17 (8.5)	17 (8.5)	21 (10.1)	113 (9.2)
Missing	0	0	0	0	0
BMI (kg/m ²)					
n (missing)	618 (0)	199 (0)	198 (1)	207 (0)	1222 (1)
Mean (SD)	24.01 (4.19)	24.02 (4.83)	23.81 (4.25)	24.19 (4.50)	24.01 (4.36)
Median	23.32	23.06	23.17	23.34	23.27
Min, Max	16, 41	16, 57	16, 37	16, 43	16, 57

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] Black or African American, American Indian, Alaska Native, Native Hawaiian or Other Pacific Islander.

[2] When more than one race is selected, Race = Multiple. A subject is counted at most once.

DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Migraine Diagnosis - n (%)					
With Aura	118 (19.1)	43 (21.6)	36 (18.1)	47 (22.7)	244 (20.0)
Without Aura	439 (71.0)	138 (69.3)	136 (68.3)	136 (65.7)	849 (69.4)
Both	61 (9.9)	18 (9.0)	27 (13.6)	23 (11.1)	129 (10.5)
Missing	0	0	0	1 (0.5)	1 (<0.1)
Migraine Disorder Duration in Years					
n (missing)	617 (1)	199 (0)	199 (0)	204 (3)	1219 (4)
Mean (SD)	18.98 (12.31)	19.79 (12.34)	18.88 (12.64)	19.91 (12.03)	19.25 (12.31)
Median	17.40	18.30	16.40	18.50	17.50
Min, Max	0, 63	1, 54	1, 58	0, 51	0, 63

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation. Percentages are calculated as $100 \times (n/N)$.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

DISEASE CHARACTERISTICS

mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Migraine associated symptoms, moderate attacks, Attack 1 - n/N (%) [1]					
Yes	501/501 (100)	164/164 (100)	149/149 (100)	162/162 (100)	976/976 (100)
Migraine associated symptoms, moderate attacks, Attack 2 - n/N (%) [1]					
Yes	474/474 (100)	145/145 (100)	155/155 (100)	153/153 (100)	927/927 (100)
Migraine associated symptoms, moderate attacks, Attack 3 - n/N (%) [1]					
Yes	431/431 (100)	135/135 (100)	143/143 (100)	144/144 (100)	853/853 (100)
Migraine associated symptoms, moderate attacks, Attack 4 - n/N (%) [1]					
Yes	393/393 (100)	132/132 (100)	136/136 (100)	131/131 (100)	792/792 (100)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation. Percentages are calculated as $100 \times (n/N)$.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 09042026

TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Migraine associated symptoms, severe attacks, Attack 1 - n/N (%) [2] Yes	111/111 (100)	34/34 (100)	49/49 (100)	44/44 (100)	238/238 (100)
Migraine associated symptoms, severe attacks, Attack 2 - n/N (%) [2] Yes	106/106 (100)	49/49 (100)	41/41 (100)	42/42 (100)	238/238 (100)
Migraine associated symptoms, severe attacks, Attack 3 - n/N (%) [2] Yes	118/118 (100)	42/42 (100)	45/45 (100)	41/41 (100)	246/246 (100)
Migraine associated symptoms, severe attacks, Attack 4 - n/N (%) [2] Yes	128/128 (100)	36/36 (100)	35/35 (100)	40/40 (100)	239/239 (100)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 09042026

TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Most bothersome symptom, Attack 1 - n/N (%)					
[3]					
Sensitivity To Light	269/612 (44.0)	90/198 (45.5)	82/198 (41.4)	94/206 (45.6)	535/1214 (44.1)
Sensitivity To Sound	147/612 (24.0)	48/198 (24.2)	52/198 (26.3)	51/206 (24.8)	298/1214 (24.5)
Nausea	196/612 (32.0)	60/198 (30.3)	64/198 (32.3)	61/206 (29.6)	381/1214 (31.4)
Missing	1	0	0	0	1
Most bothersome symptom, Attack 2 - n/N (%)					
[3]					
Sensitivity To Light	275/580 (47.4)	91/194 (46.9)	87/196 (44.4)	95/195 (48.7)	548/1165 (47.0)
Sensitivity To Sound	141/580 (24.3)	51/194 (26.3)	48/196 (24.5)	49/195 (25.1)	289/1165 (24.8)
Nausea	164/580 (28.3)	52/194 (26.8)	61/196 (31.1)	51/195 (26.2)	328/1165 (28.2)
Most bothersome symptom, Attack 3 - n/N (%)					
[3]					
Sensitivity To Light	253/550 (46.0)	87/177 (49.2)	87/188 (46.3)	88/185 (47.6)	515/1100 (46.8)
Sensitivity To Sound	132/550 (24.0)	44/177 (24.9)	42/188 (22.3)	50/185 (27.0)	268/1100 (24.4)
Nausea	165/550 (30.0)	46/177 (26.0)	59/188 (31.4)	47/185 (25.4)	317/1100 (28.8)
Most bothersome symptom, Attack 4 - n/N (%)					
[3]					
Sensitivity To Light	242/520 (46.5)	90/168 (53.6)	78/171 (45.6)	74/171 (43.3)	484/1030 (47.0)
Sensitivity To Sound	132/520 (25.4)	41/168 (24.4)	44/171 (25.7)	50/171 (29.2)	267/1030 (25.9)
Nausea	146/520 (28.1)	37/168 (22.0)	49/171 (28.7)	47/171 (27.5)	279/1030 (27.1)
Missing	1	0	0	0	1

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Average Number of Mild, Moderate or Severe Migraine Attacks Per Month Over the Past 3 Months					
n (missing)	610 (8)	195 (4)	198 (1)	204 (3)	1207 (16)
Mean (SD)	5.60 (2.13)	5.47 (2.23)	5.56 (2.00)	5.62 (2.00)	5.58 (2.10)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	2, 15	2, 14	2, 12	2, 14	2, 15
Average Number of Moderate to Severe Migraine Attacks Per Month Over the Past 3 Months					
n (missing)	618 (0)	198 (1)	199 (0)	206 (1)	1221 (2)
Mean (SD)	4.51 (1.64)	4.21 (1.54)	4.41 (1.61)	4.44 (1.66)	4.43 (1.62)
Median	4.00	4.00	4.00	4.00	4.00
Min, Max	2, 8	2, 8	2, 8	2, 8	2, 8

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation. Percentages are calculated as $100 \times (n/N)$.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Acute Migraine Treatment - n (%)					
Yes	616 (99.7)	199 (100)	199 (100)	205 (99.0)	1219 (99.7)
Triptan or Triptan Combination	416 (67.3)	135 (67.8)	130 (65.3)	134 (64.7)	815 (66.6)
Ditan	6 (1.0)	2 (1.0)	2 (1.0)	1 (0.5)	11 (0.9)
Ergot or Ergot Combination	10 (1.6)	2 (1.0)	3 (1.5)	1 (0.5)	16 (1.3)
NSAID or NSAID Combination	351 (56.8)	116 (58.3)	116 (58.3)	127 (61.4)	710 (58.1)
Opioid or Opioid Combination	24 (3.9)	11 (5.5)	9 (4.5)	3 (1.4)	47 (3.8)
Antiemetic Agent	46 (7.4)	14 (7.0)	17 (8.5)	24 (11.6)	101 (8.3)
Triptan or Diclofenac or Acetylsalicylic Acid or Ibuprofen	531 (85.9)	178 (89.4)	171 (85.9)	175 (84.5)	1055 (86.3)
Other	135 (21.8)	40 (20.1)	38 (19.1)	33 (15.9)	246 (20.1)
No	2 (0.3)	0	0	2 (1.0)	4 (0.3)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation. Percentages are calculated as $100 \times (n/N)$.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 09042026

TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Current Use of Prophylactic Medication - n (%) [4]					
Yes	141 (22.8)	44 (22.1)	45 (22.6)	48 (23.2)	278 (22.7)
Beta blocking agents	37 (26.2)	9 (20.5)	11 (24.4)	13 (27.1)	70 (25.2)
Candesartan	3 (2.1)	0	1 (2.2)	3 (6.3)	7 (2.5)
Calcium channel blocker	24 (17.0)	5 (11.4)	4 (8.9)	8 (16.7)	41 (14.7)
Flunarizine	14 (58.3)	2 (40.0)	3 (75.0)	5 (62.5)	24 (58.5)
Other calcium channel blockers	10 (41.7)	3 (60.0)	1 (25.0)	4 (50.0)	18 (43.9)
Anticonvulsants	52 (36.9)	15 (34.1)	16 (35.6)	14 (29.2)	97 (34.9)
Topiramate	41 (78.8)	13 (86.7)	12 (75.0)	10 (71.4)	76 (78.4)
Other anticonvulsants	14 (26.9)	2 (13.3)	4 (25.0)	4 (28.6)	24 (24.7)
Antidepressants	40 (28.4)	16 (36.4)	18 (40.0)	17 (35.4)	91 (32.7)
Tricyclic antidepressants	32 (80.0)	14 (87.5)	18 (100)	15 (88.2)	79 (86.8)
Amitriptyline	32 (100)	13 (92.9)	18 (100)	13 (86.7)	76 (96.2)
Amitriptyline; Perphenazine [5]	0	1 (7.1)	0	0	1 (1.3)
Venlafaxine	8 (20.0)	2 (12.5)	0	1 (5.9)	11 (12.1)
Other antidepressants	1 (2.5)	0	0	2 (11.8)	3 (3.3)
Vitamins / dietary supplements	6 (4.3)	0	1 (2.2)	2 (4.2)	9 (3.2)
Magnesium	2 (1.4)	1 (2.3)	0	1 (2.1)	4 (1.4)
Botulinum toxin	11 (7.8)	6 (13.6)	4 (8.9)	4 (8.3)	25 (9.0)
Botulinum toxin A	10 (90.9)	4 (66.7)	3 (75.0)	3 (75.0)	20 (80.0)
Botulinum toxin (not otherwise specified)	1 (9.1)	2 (33.3)	1 (25.0)	1 (25.0)	5 (20.0)
NSAID	2 (1.4)	0	0	0	2 (0.7)
ASA	1 (50.0)	0	0	0	1 (50.0)
Other NSAID	1 (50.0)	0	0	0	1 (50.0)
Other	5 (3.5)	2 (4.5)	2 (4.4)	0	9 (3.2)
No	477 (77.2)	155 (77.9)	154 (77.4)	159 (76.8)	945 (77.3)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DISEASE CHARACTERISTICS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Use of Prophylactic Medication (at any time)					
- n (%)					
Yes	293 (47.4)	91 (45.7)	89 (44.7)	102 (49.3)	575 (47.0)
No	325 (52.6)	108 (54.3)	110 (55.3)	105 (50.7)	648 (53.0)
Missing	0	0	0	0	0
Response to Triptans - n (%)					
Triptan Unsuitable	90 (14.6)	30 (15.1)	33 (16.6)	35 (16.9)	188 (15.4)
Triptan Experienced	418 (67.6)	134 (67.3)	126 (63.3)	137 (66.2)	815 (66.6)
Triptan Naïve	110 (17.8)	35 (17.6)	40 (20.1)	35 (16.9)	220 (18.0)
Used >=2 Triptans (at any time) - n (%)					
Yes	59 (9.5)	17 (8.5)	21 (10.6)	22 (10.6)	119 (9.7)
No	559 (90.5)	182 (91.5)	178 (89.4)	185 (89.4)	1104 (90.3)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

[1] N=Number of subjects with moderate symptoms at baseline for the respective attack.

[2] N=Number of subjects with severe symptoms at baseline for the respective attack.

[3] N=Number of subjects treated with study drug for the specific migraine attack and had available assessments during the DB treatment period.

[4] Percentages in a subcategory were computed relative to the number of subjects in the higher level category.

[5] CGRP-targeted preventive therapy was not allowed per protocol.

ASA=Acetylsalicylic acid, CGRP=Calcitonin gene-related peptide, DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population, NSAID=Nonsteroidal anti-inflammatory drug, SD=Standard deviation. Percentages are calculated as $100 \times (n/N)$.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

NON-PHARMACOLOGICAL THERAPIES

mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
At least one Non-Pharmacological Therapy - n (%)					
Yes	11 (1.8)	4 (2.0)	3 (1.5)	6 (2.9)	24 (2.0)
No	607 (98.2)	195 (98.0)	196 (98.5)	201 (97.1)	1199 (98.0)
Non-Pharmacological Therapies - n (%)					
Botulinum Toxin	2 (0.3)	0	2 (1.0)	0	4 (0.3)
Interventional Pain Management	3 (0.5)	2 (1.0)	1 (0.5)	0	6 (0.5)
Surgical Intervention	3 (0.5)	1 (0.5)	0	1 (0.5)	5 (0.4)
Physical Modalities	4 (0.6)	1 (0.5)	0	5 (2.4)	10 (0.8)
Acupuncture	3 (0.5)	1 (0.5)	0	4 (1.9)	8 (0.7)
Heat Therapy	0	0	0	1 (0.5)	1 (<0.1)
Laser Therapy	1 (0.2)	0	0	0	1 (<0.1)
Manual Therapy Techniques	1 (0.2)	1 (0.5)	0	2 (1.0)	4 (0.3)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects within a specific category, N=Number of subjects within the population

Percentages are calculated as 100 x (n/N).

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.5
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIMING OF ATTACKS
 SAF1 ANALYSIS SET

	Treatment Sequence 1 (N=623)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=202)	Treatment Sequence 4 (N=208)	Total (N=1232)
Time between attacks (days)					
Attack 1 - 2 or end of DB period					
n (missing)	621 (2)	199 (0)	200 (2)	207 (1)	1227 (5)
Mean (SD)	19.57 (19.27)	16.88 (14.57)	17.42 (16.16)	18.10 (17.00)	18.53 (17.73)
Median	13.00	11.00	11.00	12.00	12.00
Min, Max	2, 151	2, 79	2, 85	2, 106	2, 151
Attack 2 - 3 or end of DB period					
n (missing)	586 (37)	194 (5)	198 (4)	196 (12)	1174 (58)
Mean (SD)	17.52 (14.84)	17.56 (16.75)	16.37 (13.64)	18.09 (18.15)	17.43 (15.56)
Median	12.00	11.00	12.00	11.00	12.00
Min, Max	0, 104	2, 82	3, 78	2, 143	0, 143
Attack 3 - 4 or end of DB period					
n (missing)	554 (69)	179 (20)	190 (12)	185 (23)	1108 (124)
Mean (SD)	17.34 (15.48)	17.30 (14.56)	16.58 (13.50)	17.78 (15.06)	17.28 (14.93)
Median	12.00	12.00	13.00	13.00	12.00
Min, Max	2, 114	2, 95	2, 70	2, 97	2, 114
Attack 4 - end of DB period					
n (missing)	520 (103)	168 (31)	171 (31)	169 (39)	1028 (204)
Mean (SD)	6.84 (5.97)	6.78 (5.39)	6.63 (4.80)	7.19 (6.82)	6.86 (5.84)
Median	6.00	6.00	6.00	6.00	6.00
Min, Max	1, 67	1, 43	1, 33	1, 56	1, 67
All attacks					
n (missing)	2281 (211)	740 (56)	759 (49)	757 (75)	4537 (391)
Mean (SD)	15.60 (15.72)	14.87 (14.39)	14.50 (13.63)	15.58 (15.80)	15.30 (15.19)
Median	10.00	9.00	9.00	9.00	9.00
Min, Max	0, 151	1, 95	1, 85	1, 143	0, 151

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

Time between attacks was computed as number of days between start of one attack and start of following attack. In case no following attack was available, the number of days to end of DB treatment period was computed.

DB=Double blind, n=Number of observed attacks, N=Number of subjects in the SAF1 population for the respective treatment sequence, SAF1=Safety analysis set of the DB phase, SD=Standard deviation

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

TABLE 4.1.6
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF STUDY PARTICIPATION
 SAF1 ANALYSIS SET

	Treatment Sequence 1 (N=623)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=202)	Treatment Sequence 4 (N=208)	Total (N=1232)
Study Participation					
Double-blind Treatment Period (Days)					
n	623	199	202	208	1232
Mean (SD)	73.93 (31.56)	72.32 (32.47)	71.10 (29.96)	74.76 (32.77)	73.34 (31.64)
Median	65.00	64.00	62.00	65.00	65.00
Q1, Q3	49.00, 106.00	46.00, 108.00	49.00, 98.00	49.00, 108.50	49.00, 106.00
Min, Max	11, 192	4, 167	19, 145	16, 175	4, 192
Duration Interval (Days) - n1 (%)					
>= 28	609 (97.8)	195 (98.0)	194 (96.0)	199 (95.7)	1197 (97.2)
>= 56	431 (69.2)	122 (61.3)	136 (67.3)	143 (68.8)	832 (67.5)
>= 84	243 (39.0)	73 (36.7)	70 (34.7)	87 (41.8)	473 (38.4)
>= 112	112 (18.0)	42 (21.1)	37 (18.3)	45 (21.6)	236 (19.2)

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

DB=Double blind, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, Q1=First quartile, Q3=Third quartile, SAF1=Safety analysis set of the DB phase, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.7
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR ADVERSE EVENTS
 SAF1 ANALYSIS SET

	Treatment Sequence 1 (N=623)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=202)	Treatment Sequence 4 (N=208)	Total (N=1232)
Adverse Events					
Double-blind Treatment Period (Days)					
n	623	199	202	208	1232
Mean (SD)	58.10 (27.01)	56.24 (26.68)	55.54 (24.55)	58.00 (27.48)	57.36 (26.64)
Median	53.00	51.00	51.00	53.00	52.00
Q1, Q3	37.00, 76.00	35.00, 72.00	37.00, 72.00	37.00, 75.00	37.00, 74.00
Min, Max	3, 192	3, 156	1, 120	3, 166	1, 192
Duration Interval (Days) - n1 (%)					
>= 28	570 (91.5)	180 (90.5)	178 (88.1)	186 (89.4)	1114 (90.4)
>= 56	279 (44.8)	85 (42.7)	83 (41.1)	98 (47.1)	545 (44.2)
>= 84	124 (19.9)	38 (19.1)	33 (16.3)	36 (17.3)	231 (18.8)
>= 112	19 (3.0)	4 (2.0)	4 (2.0)	5 (2.4)	32 (2.6)

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

DB=Double blind, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, Q1=First quartile, Q3=Third quartile, SAF1=Safety analysis set of the DB phase, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of follow-up for adverse events was calculated as last day in DB period - day of first treatment in DB period + 1.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Pain Freedom					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Sustained pain freedom					
Double-blind Treatment Period (Days)					
n	543	176	176	184	1079
Mean (SD)	59.73 (29.60)	56.82 (30.49)	54.48 (29.49)	49.58 (29.53)	56.67 (29.91)
Median	54.00	50.50	51.00	44.00	51.00
Q1, Q3	37.00, 82.00	31.00, 79.50	31.00, 78.50	27.00, 69.50	33.00, 79.00
Min, Max	3, 170	6, 117	3, 130	4, 114	3, 170
Duration Interval (Days) - n1 (%)					
>= 28	477 (77.2)	143 (71.9)	140 (70.4)	136 (65.7)	896 (73.3)
>= 56	255 (41.3)	73 (36.7)	75 (37.7)	65 (31.4)	468 (38.3)
>= 84	129 (20.9)	42 (21.1)	37 (18.6)	33 (15.9)	241 (19.7)
>= 112	24 (3.9)	8 (4.0)	6 (3.0)	5 (2.4)	43 (3.5)
Missing	75	23	23	23	144

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1= Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Sustained pain freedom 4h					
Double-blind Treatment Period (Days)					
n	536	174	174	180	1064
Mean (SD)	59.02 (29.88)	55.33 (30.47)	53.09 (30.08)	49.12 (29.65)	55.77 (30.16)
Median	53.00	49.00	50.50	43.50	51.00
Q1, Q3	36.00, 82.00	31.00, 74.00	29.00, 78.00	27.00, 69.50	32.50, 78.50
Min, Max	3, 170	5, 117	3, 130	3, 114	3, 170
Duration Interval (Days) - n1 (%)					
>= 28	469 (75.9)	140 (70.4)	136 (68.3)	131 (63.3)	876 (71.6)
>= 56	248 (40.1)	68 (34.2)	72 (36.2)	63 (30.4)	451 (36.9)
>= 84	125 (20.2)	40 (20.1)	35 (17.6)	31 (15.0)	231 (18.9)
>= 112	23 (3.7)	7 (3.5)	6 (3.0)	5 (2.4)	41 (3.4)
Missing	82	25	25	27	159

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1= Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Pain Relief					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1= Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Sustained pain relief					
Double-blind Treatment Period (Days)					
n	543	176	176	184	1079
Mean (SD)	59.73 (29.60)	56.82 (30.49)	54.48 (29.49)	49.58 (29.53)	56.67 (29.91)
Median	54.00	50.50	51.00	44.00	51.00
Q1, Q3	37.00, 82.00	31.00, 79.50	31.00, 78.50	27.00, 69.50	33.00, 79.00
Min, Max	3, 170	6, 117	3, 130	4, 114	3, 170
Duration Interval (Days) - n1 (%)					
>= 28	477 (77.2)	143 (71.9)	140 (70.4)	136 (65.7)	896 (73.3)
>= 56	255 (41.3)	73 (36.7)	75 (37.7)	65 (31.4)	468 (38.3)
>= 84	129 (20.9)	42 (21.1)	37 (18.6)	33 (15.9)	241 (19.7)
>= 112	24 (3.9)	8 (4.0)	6 (3.0)	5 (2.4)	43 (3.5)
Missing	75	23	23	23	144

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Sustained pain relief 4h					
Double-blind Treatment Period (Days)					
n	536	174	174	180	1064
Mean (SD)	59.02 (29.88)	55.33 (30.47)	53.09 (30.08)	49.12 (29.65)	55.77 (30.16)
Median	53.00	49.00	50.50	43.50	51.00
Q1, Q3	36.00, 82.00	31.00, 74.00	29.00, 78.00	27.00, 69.50	32.50, 78.50
Min, Max	3, 170	5, 117	3, 130	3, 114	3, 170
Duration Interval (Days) - n1 (%)					
>= 28	469 (75.9)	140 (70.4)	136 (68.3)	131 (63.3)	876 (71.6)
>= 56	248 (40.1)	68 (34.2)	72 (36.2)	63 (30.4)	451 (36.9)
>= 84	125 (20.2)	40 (20.1)	35 (17.6)	31 (15.0)	231 (18.9)
>= 112	23 (3.7)	7 (3.5)	6 (3.0)	5 (2.4)	41 (3.4)
Missing	82	25	25	27	159

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Absence of the MBS					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Absence of Photophobia					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Absence of Phonophobia					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 01042026

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Absence of Nausea					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 01042026

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Absence of Vomiting					
Double-blind Treatment Period (Days)					
n	617	199	199	207	1222
Mean (SD)	63.67 (29.62)	62.29 (29.60)	64.03 (28.04)	62.07 (28.96)	63.23 (29.23)
Median	58.00	55.00	57.00	55.00	57.00
Q1, Q3	41.00, 86.00	39.00, 86.00	43.00, 85.00	39.00, 87.00	41.00, 86.00
Min, Max	3, 172	3, 127	8, 130	11, 140	3, 172
Duration Interval (Days) - n1 (%)					
>= 28	560 (90.6)	176 (88.4)	182 (91.5)	188 (90.8)	1106 (90.4)
>= 56	332 (53.7)	97 (48.7)	109 (54.8)	101 (48.8)	639 (52.2)
>= 84	173 (28.0)	52 (26.1)	55 (27.6)	56 (27.1)	336 (27.5)
>= 112	31 (5.0)	12 (6.0)	12 (6.0)	11 (5.3)	66 (5.4)
Missing	1	0	0	0	1

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 01042026

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
Rescue Medication Use					
Double-blind Treatment Period (Days)					
n	618	199	199	207	1223
Mean (SD)	63.93 (29.56)	62.49 (29.59)	64.33 (28.11)	62.67 (29.19)	63.55 (29.25)
Median	58.00	55.00	58.00	55.00	57.00
Q1, Q3	41.00, 87.00	40.00, 86.00	43.00, 85.00	39.00, 88.00	41.00, 86.00
Min, Max	3, 174	3, 127	9, 130	12, 142	3, 174
Duration Interval (Days) - n1 (%)					
>= 28	563 (91.1)	177 (88.9)	182 (91.5)	189 (91.3)	1111 (90.8)
>= 56	336 (54.4)	98 (49.2)	109 (54.8)	103 (49.8)	646 (52.8)
>= 84	174 (28.2)	53 (26.6)	56 (28.1)	57 (27.5)	340 (27.8)
>= 112	33 (5.3)	13 (6.5)	13 (6.5)	13 (6.3)	72 (5.9)

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 01042026

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
PGI-C					
Double-blind Treatment Period (Days)					
n	617	198	198	207	1220
Mean (SD)	61.43 (29.88)	60.18 (29.99)	61.44 (27.83)	59.59 (28.97)	60.92 (29.39)
Median	56.00	53.00	55.00	52.00	55.00
Q1, Q3	39.00, 84.00	36.00, 84.00	40.00, 83.00	35.00, 84.00	38.00, 84.00
Min, Max	1, 172	1, 125	8, 128	11, 140	1, 172
Duration Interval (Days) - n1 (%)					
>= 28	538 (87.1)	170 (85.4)	176 (88.4)	184 (88.9)	1068 (87.3)
>= 56	316 (51.1)	89 (44.7)	98 (49.2)	94 (45.4)	597 (48.8)
>= 84	158 (25.6)	50 (25.1)	46 (23.1)	52 (25.1)	306 (25.0)
>= 112	16 (2.6)	8 (4.0)	9 (4.5)	7 (3.4)	40 (3.3)
Missing	1	1	1	0	3

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
CFS Ability to think clearly					
Double-blind Treatment Period (Days)					
n	618	199	199	207	1223
Mean (SD)	62.13 (29.54)	60.68 (29.56)	62.55 (28.12)	60.89 (29.18)	61.75 (29.23)
Median	56.50	53.00	57.00	54.00	56.00
Q1, Q3	39.00, 85.00	38.00, 84.00	41.00, 83.00	37.00, 86.00	39.00, 85.00
Min, Max	2, 172	1, 125	7, 129	11, 140	1, 172
Duration Interval (Days) - n1 (%)					
>= 28	552 (89.3)	173 (86.9)	178 (89.4)	186 (89.9)	1089 (89.0)
>= 56	324 (52.4)	92 (46.2)	101 (50.8)	99 (47.8)	616 (50.4)
>= 84	160 (25.9)	51 (25.6)	49 (24.6)	55 (26.6)	315 (25.8)
>= 112	18 (2.9)	8 (4.0)	11 (5.5)	7 (3.4)	44 (3.6)

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
EQ 5D VAS					
Double-blind Treatment Period (Days)					
n	618	199	199	207	1223
Mean (SD)	62.85 (29.58)	61.41 (29.60)	63.24 (28.08)	61.57 (29.15)	62.46 (29.24)
Median	57.00	54.00	57.00	54.00	56.00
Q1, Q3	40.00, 85.00	38.00, 85.00	42.00, 84.00	38.00, 87.00	40.00, 85.00
Min, Max	2, 172	2, 126	8, 129	10, 140	2, 172
Duration Interval (Days) - n1 (%)					
>= 28	555 (89.8)	174 (87.4)	181 (91.0)	187 (90.3)	1097 (89.7)
>= 56	329 (53.2)	96 (48.2)	107 (53.8)	99 (47.8)	631 (51.6)
>= 84	164 (26.5)	52 (26.1)	53 (26.6)	57 (27.5)	326 (26.7)
>= 112	24 (3.9)	10 (5.0)	13 (6.5)	9 (4.3)	56 (4.6)

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
MQoLQ					
Double-blind Treatment Period (Days)					
n	602	193	193	200	1188
Mean (SD)	62.08 (29.21)	60.90 (29.62)	60.75 (28.42)	60.00 (28.44)	61.32 (29.00)
Median	57.00	54.00	56.00	53.00	56.00
Q1, Q3	39.00, 84.00	38.00, 84.00	40.00, 81.00	37.00, 85.50	39.00, 84.00
Min, Max	2, 169	2, 126	4, 129	5, 117	2, 169
Duration Interval (Days) - n1 (%)					
>= 28	541 (87.5)	166 (83.4)	170 (85.4)	180 (87.0)	1057 (86.4)
>= 56	313 (50.6)	94 (47.2)	100 (50.3)	92 (44.4)	599 (49.0)
>= 84	155 (25.1)	50 (25.1)	45 (22.6)	53 (25.6)	303 (24.8)
>= 112	22 (3.6)	9 (4.5)	10 (5.0)	6 (2.9)	47 (3.8)
Missing	16	6	6	7	35

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 01042026

TABLE 4.1.8
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 DURATION OF FOLLOW-UP FOR EFFICACY ENDPOINTS
 mITT1 ANALYSIS SET

	Treatment Sequence 1 (N=618)	Treatment Sequence 2 (N=199)	Treatment Sequence 3 (N=199)	Treatment Sequence 4 (N=207)	Total (N=1223)
FDS normal function					
Double-blind Treatment Period (Days)					
n	618	199	199	207	1223
Mean (SD)	62.13 (29.54)	60.68 (29.56)	62.55 (28.12)	60.89 (29.18)	61.75 (29.23)
Median	56.50	53.00	57.00	54.00	56.00
Q1, Q3	39.00, 85.00	38.00, 84.00	41.00, 83.00	37.00, 86.00	39.00, 85.00
Min, Max	2, 172	1, 125	7, 129	11, 140	1, 172
Duration Interval (Days) - n1 (%)					
>= 28	552 (89.3)	173 (86.9)	178 (89.4)	186 (89.9)	1089 (89.0)
>= 56	324 (52.4)	92 (46.2)	101 (50.8)	99 (47.8)	616 (50.4)
>= 84	160 (25.9)	51 (25.6)	49 (24.6)	55 (26.6)	315 (25.8)
>= 112	18 (2.9)	8 (4.0)	11 (5.5)	7 (3.4)	44 (3.6)

The mITT1 population includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life 5 Dimensions Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MBS=Most bothersome symptom, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects within a specific category, n1=Number of subjects with duration in the specified interval, N=Number of subjects within the population, PGI-C=Patient Global Impression of Change, Q1=First quartile, Q3=Third quartile, SD=Standard deviation
 Percentages are calculated as 100 x (n/N).

Duration of study participation was calculated as last day in DB period - first day in DB period + 1.

For MQoLQ the date of the first and last observation in any of the domains was used for the computation of duration of follow-up.

The planned treatment sequences were used in the table. Subjects were randomized to placebo: Treatment Sequence 1, Attack 1; Treatment Sequence 2, Attack 2; Treatment Sequence 3, Attack 3; Treatment Sequence 4, Attack 4. Subjects were randomized to atogepant for all other attacks.

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TABLE 4.1.9.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME TO RESCUE MEDICATION
 mITT1 ANALYSIS SET

	Placebo	Atogepant
Attack 1, N	613	602
Patients who took at least one rescue medication, n (%)	342 (55.8)	105 (17.4)
Time to first rescue medication (hours)		
Mean (SD)	6.19 (7.60)	8.26 (11.32)
Median	3.33	2.93
Min, Max	0, 47	0, 47
Attack 2, N	194	971
Patients who took at least one rescue medication, n (%)	113 (58.2)	192 (19.8)
Time to first rescue medication (hours)		
Mean (SD)	4.74 (6.17)	6.68 (9.45)
Median	2.85	2.82
Min, Max	1, 46	1, 47
Attack 3, N	188	912
Patients who took at least one rescue medication, n (%)	111 (59.0)	160 (17.5)
Time to first rescue medication (hours)		
Mean (SD)	5.38 (6.90)	6.33 (8.65)
Median	3.17	2.83
Min, Max	0, 40	1, 48
Attack 4, N	171	860
Patients who took at least one rescue medication, n (%)	98 (57.3)	148 (17.2)
Time to first rescue medication (hours)		
Mean (SD)	6.09 (7.63)	7.74 (11.22)
Median	3.26	2.85
Min, Max	2, 45	0, 47
Overall, N	1166	1187
Patients who took at least one rescue medication, n (%)	664 (56.9)	449 (37.8)
Time to first rescue medication (hours)		
n1	664	605
Mean (SD)	5.79 (7.27)	7.12 (10.06)
Median	3.12	2.83
Min, Max	0, 47	0, 48

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects who took at least one rescue medication, n1=Number of attacks for which at least one rescue medication was taken during the DB phase; subjects can be counted multiple times if rescue medication was taken in multiple attacks, N=Number of subjects who received treatment for the attack; for the overall assessment, the number of subjects who received treatment for at least one attack, SD=Standard deviation

Percentages are calculated as 100 x (n/N).

Time to first rescue medication is the time from intake of study medication to time of first rescue medication in the same attack. Only rescue medication taken within 48 hours of the study medication is considered. Subjects were analyzed as randomized.

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TABLE 4.1.9.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

RESCUE MEDICATION TAKEN

MITT1 ANALYSIS SET

	Placebo	Atogepant
Rescue medications taken within 48 hours of DB dose, n (%)		
Any medication, N	975	758
ACECLOFENAC	1 (0.1)	0
ACETAMINOPHEN/PARACETAMOL	32 (3.3)	31 (4.1)
ACETAMINOPHEN/PARACETAMOL, ACETYLSALICYLIC ACID AND CAFFEINE	11 (1.1)	11 (1.5)
ACETYLSALICYLIC ACID	3 (0.3)	3 (0.4)
ACETYLSALICYLIC ACID AND CAFFEINE	0	1 (0.1)
ALMOTRIPTAN	26 (2.7)	22 (2.9)
CODEINE AND ACETAMINOPHEN/PARACETAMOL	3 (0.3)	6 (0.8)
CODEINE, ACETAMINOPHEN/PARACETAMOL AND BUCCLIZINE	0	1 (0.1)
CODEINE, ACETAMINOPHEN/PARACETAMOL AND CAFFEINE	5 (0.5)	11 (1.5)
DEXIBUPROFEN	5 (0.5)	4 (0.5)
DEKETO PROFEN	10 (1.0)	7 (0.9)
DICLOFENAC	26 (2.7)	30 (4.0)
DIHYDROERGOTAMINE	0	1 (0.1)
DOMPERIDONE	13 (1.3)	16 (2.1)
ELETRIPTAN	56 (5.7)	49 (6.5)
ERGOTAMINE	2 (0.2)	2 (0.3)
FROVATRIPTAN	8 (0.8)	9 (1.2)
HYDROCODONE AND ACETAMINOPHEN/PARACETAMOL	1 (0.1)	1 (0.1)
IBUPROFEN	99 (10.2)	61 (8.0)
IBUPROFEN, ACETYLSALICYLIC ACID AND CAFFEINE	3 (0.3)	4 (0.5)
INDOMETHACIN	21 (2.2)	16 (2.1)
KETOPROFEN	10 (1.0)	7 (0.9)
LASMIDITAN	3 (0.3)	4 (0.5)
LOXOPROFEN	13 (1.3)	8 (1.1)
METAMIZOLE	10 (1.0)	11 (1.5)
METOCLOPRAMIDE	9 (0.9)	5 (0.7)
NAPROXEN	32 (3.3)	22 (2.9)
NARATRIPTAN	34 (3.5)	28 (3.7)
OTHER ANTIEMETIC	1 (0.1)	2 (0.3)
OTHER ERGOT / ERGOT DERIVATIVE CONTAINING MEDICATION INCLUDING COMBINATION MEDICATIONS	3 (0.3)	1 (0.1)
OTHER NOT LISTED	83 (8.5)	73 (9.6)

The MITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

DB=Double blind, MITT1=Modified intent to treat population of the DB phase, n=Number of medications taken within a specific category, N=Number of times a rescue medication was taken within 48 hours of the study medication throughout the DB phase

Percentages are calculated as 100 x (n/N).

Only rescue medication taken within 48 hours of the study medication is considered. Subjects were analyzed as randomized.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 08042026

TABLE 4.1.9.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RESCUE MEDICATION TAKEN
 MITT1 ANALYSIS SET

	Placebo	Atogepant
OTHER NSAID OR ANALGESIC	38 (3.9)	33 (4.4)
OTHER NSAID OR ANALGESIC COMBINATION MEDICATION EXCLUDING OPIOID OR ERGOT COMBINATION	6 (0.6)	10 (1.3)
RIZATRIPTAN	92 (9.4)	64 (8.4)
SUMATRIPTAN	203 (20.8)	142 (18.7)
SUMATRIPTAN AND NAPROXEN	6 (0.6)	3 (0.4)
TRAMADOL	0	1 (0.1)
ZOLMITRIPTAN	107 (11.0)	58 (7.7)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

DB=Double blind, mITT1=Modified intent to treat population of the DB phase, n=Number of medications taken within a specific category, N=Number of times a rescue medication was taken within 48 hours of the study medication throughout the DB phase

Percentages are calculated as 100 x (n/N).

Only rescue medication taken within 48 hours of the study medication is considered. Subjects were analyzed as randomized.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 08042026

TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
PGI-C	Attack 1, N	605	618
	2 hours after the DB dose, n (%)	584 (96.5)	600 (97.1)
	Attack 2, N	1024	199
	2 hours after the DB dose, n (%)	934 (91.2)	184 (92.5)
	Attack 3, N	1024	199
	2 hours after the DB dose, n (%)	889 (86.8)	179 (89.9)
	Attack 4, N	1016	207
	2 hours after the DB dose, n (%)	824 (81.1)	161 (77.8)
	At least one attack, N	1223	1223
	2 hours after the DB dose, n (%)	1184 (96.8)	1124 (91.9)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
 Percentages are calculated as 100 x (n/N).

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 08042026

TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
CFS Ability to think clearly	Attack 1, N	605	618
	Baseline, n (%)	602 (99.5)	612 (99.0)
	2 hours after the DB dose, n (%)	581 (96.0)	599 (96.9)
	4 hours after the DB dose, n (%)	561 (92.7)	571 (92.4)
	8 hours after the DB dose, n (%)	520 (86.0)	528 (85.4)
	Baseline plus at least one observation, n (%)	591 (97.7)	606 (98.1)
	Attack 2, N	1024	199
	Baseline, n (%)	971 (94.8)	194 (97.5)
	2 hours after the DB dose, n (%)	930 (90.8)	183 (92.0)
	4 hours after the DB dose, n (%)	910 (88.9)	175 (87.9)
	8 hours after the DB dose, n (%)	821 (80.2)	156 (78.4)
	Baseline plus at least one observation, n (%)	958 (93.6)	191 (96.0)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
 Percentages are calculated as 100 x (n/N).

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 08042026

TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
CFS Ability to think clearly	Attack 3, N	1024	199
	Baseline, n (%)	912 (89.1)	188 (94.5)
	2 hours after the DB dose, n (%)	885 (86.4)	178 (89.4)
	4 hours after the DB dose, n (%)	838 (81.8)	179 (89.9)
	8 hours after the DB dose, n (%)	787 (76.9)	167 (83.9)
	Baseline plus at least one observation, n (%)	903 (88.2)	187 (94.0)
	Attack 4, N	1016	207
	Baseline, n (%)	859 (84.5)	171 (82.6)
	2 hours after the DB dose, n (%)	821 (80.8)	160 (77.3)
	4 hours after the DB dose, n (%)	792 (78.0)	159 (76.8)
	8 hours after the DB dose, n (%)	725 (71.4)	146 (70.5)
	Baseline plus at least one observation, n (%)	847 (83.4)	170 (82.1)
	At least one attack, N	1223	1223
	2 hours after the DB dose, n (%)	1184 (96.8)	1120 (91.6)
	4 hours after the DB dose, n (%)	1169 (95.6)	1084 (88.6)
	8 hours after the DB dose, n (%)	1134 (92.7)	997 (81.5)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint	Atogepant	Placebo
EQ 5D VAS		
Attack 1, N	605	618
Baseline, n (%)	602 (99.5)	612 (99.0)
24 hours after the DB dose, n (%)	558 (92.2)	565 (91.4)
Baseline plus at least one observation, n (%)	558 (92.2)	565 (91.4)
Attack 2, N	1024	199
Baseline, n (%)	971 (94.8)	194 (97.5)
24 hours after the DB dose, n (%)	893 (87.2)	174 (87.4)
Baseline plus at least one observation, n (%)	893 (87.2)	174 (87.4)
Attack 3, N	1024	199
Baseline, n (%)	912 (89.1)	188 (94.5)
24 hours after the DB dose, n (%)	853 (83.3)	168 (84.4)
Baseline plus at least one observation, n (%)	853 (83.3)	168 (84.4)
Attack 4, N	1016	207
Baseline, n (%)	859 (84.5)	171 (82.6)
24 hours after the DB dose, n (%)	800 (78.7)	153 (73.9)
Baseline plus at least one observation, n (%)	800 (78.7)	153 (73.9)
At least one attack, N	1223	1223
24 hours after the DB dose, n (%)	1148 (93.9)	1060 (86.7)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
FDS normal function	Attack 1, N	605	618
	Baseline, n (%)	601 (99.3)	611 (98.9)
	2 hours after the DB dose, n (%)	581 (96.0)	599 (96.9)
	4 hours after the DB dose, n (%)	562 (92.9)	572 (92.6)
	8 hours after the DB dose, n (%)	521 (86.1)	528 (85.4)
	Baseline plus at least one observation, n (%)	590 (97.5)	605 (97.9)
	Attack 2, N	1024	199
	Baseline, n (%)	971 (94.8)	193 (97.0)
	2 hours after the DB dose, n (%)	930 (90.8)	183 (92.0)
	4 hours after the DB dose, n (%)	910 (88.9)	175 (87.9)
	8 hours after the DB dose, n (%)	821 (80.2)	156 (78.4)
	Baseline plus at least one observation, n (%)	958 (93.6)	190 (95.5)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
FDS normal function	Attack 3, N	1024	199
	Baseline, n (%)	911 (89.0)	188 (94.5)
	2 hours after the DB dose, n (%)	885 (86.4)	178 (89.4)
	4 hours after the DB dose, n (%)	838 (81.8)	179 (89.9)
	8 hours after the DB dose, n (%)	787 (76.9)	167 (83.9)
	Baseline plus at least one observation, n (%)	902 (88.1)	187 (94.0)
	Attack 4, N	1016	207
	Baseline, n (%)	858 (84.4)	171 (82.6)
	2 hours after the DB dose, n (%)	821 (80.8)	160 (77.3)
	4 hours after the DB dose, n (%)	792 (78.0)	159 (76.8)
	8 hours after the DB dose, n (%)	725 (71.4)	146 (70.5)
	Baseline plus at least one observation, n (%)	846 (83.3)	170 (82.1)
	At least one attack, N	1223	1223
	2 hours after the DB dose, n (%)	1184 (96.8)	1118 (91.4)
	4 hours after the DB dose, n (%)	1169 (95.6)	1083 (88.6)
	8 hours after the DB dose, n (%)	1134 (92.7)	996 (81.4)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
MQoLQ work functioning	Attack 1, N	605	618
	24 hours after the DB dose, n (%)	558 (92.2)	565 (91.4)
	Attack 2, N	1024	199
	24 hours after the DB dose, n (%)	894 (87.3)	174 (87.4)
	Attack 3, N	1024	199
	24 hours after the DB dose, n (%)	855 (83.5)	167 (83.9)
	Attack 4, N	1016	207
	24 hours after the DB dose, n (%)	801 (78.8)	153 (73.9)
	At least one attack, N	1223	1223
	24 hours after the DB dose, n (%)	1150 (94.0)	1059 (86.6)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
 Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
MQoLQ social functioning	Attack 1, N	605	618
	24 hours after the DB dose, n (%)	558 (92.2)	565 (91.4)
	Attack 2, N	1024	199
	24 hours after the DB dose, n (%)	894 (87.3)	174 (87.4)
	Attack 3, N	1024	199
	24 hours after the DB dose, n (%)	855 (83.5)	167 (83.9)
	Attack 4, N	1016	207
	24 hours after the DB dose, n (%)	801 (78.8)	153 (73.9)
	At least one attack, N	1223	1223
	24 hours after the DB dose, n (%)	1150 (94.0)	1059 (86.6)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
 Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
MQoLQ energy vitality	Attack 1, N	605	618
	24 hours after the DB dose, n (%)	558 (92.2)	565 (91.4)
	Attack 2, N	1024	199
	24 hours after the DB dose, n (%)	894 (87.3)	174 (87.4)
	Attack 3, N	1024	199
	24 hours after the DB dose, n (%)	855 (83.5)	167 (83.9)
	Attack 4, N	1016	207
	24 hours after the DB dose, n (%)	801 (78.8)	153 (73.9)
	At least one attack, N	1223	1223
	24 hours after the DB dose, n (%)	1150 (94.0)	1059 (86.6)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
MQoLQ feelings concerns	Attack 1, N	605	618
	24 hours after the DB dose, n (%)	558 (92.2)	565 (91.4)
	Attack 2, N	1024	199
	24 hours after the DB dose, n (%)	894 (87.3)	174 (87.4)
	Attack 3, N	1024	199
	24 hours after the DB dose, n (%)	855 (83.5)	167 (83.9)
	Attack 4, N	1016	207
	24 hours after the DB dose, n (%)	801 (78.8)	153 (73.9)
	At least one attack, N	1223	1223
	24 hours after the DB dose, n (%)	1150 (94.0)	1059 (86.6)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
 Percentages are calculated as 100 x (n/N).

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TABLE 4.1.10.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 RETURN RATES OF PRO ENDPOINTS
 mITT1 ANALYSIS SET

Endpoint		Atogepant	Placebo
MQoLQ migraine symptoms	Attack 1, N	605	618
	24 hours after the DB dose, n (%)	558 (92.2)	565 (91.4)
	Attack 2, N	1024	199
	24 hours after the DB dose, n (%)	894 (87.3)	174 (87.4)
	Attack 3, N	1024	199
	24 hours after the DB dose, n (%)	855 (83.5)	167 (83.9)
	Attack 4, N	1016	207
	24 hours after the DB dose, n (%)	801 (78.8)	153 (73.9)
	At least one attack, N	1223	1223
	24 hours after the DB dose, n (%)	1150 (94.0)	1059 (86.6)

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CFS=Cognitive Function Scale, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, FDS=Functional Disability Scale, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observations at the given timepoint(s), N=Number of subjects in the mITT1 population for the respective attack(s), PGI-C=Patient Global Impression of Change
 Percentages are calculated as 100 x (n/N).

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TABLE 4.2.1.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN FREEDOM, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	80 (13.1) 12 (2.0)	602	147 (24.4) 18 (3.0)	2.38 [1.78, 3.19]	2.04 [1.55, 2.54]	12.63 [8.52, 16.73]	<0.0001
Attack 2	194	11 (5.7) 10 (5.2)	971	290 (29.9) 37 (3.8)	7.23 [3.96, 13.22]	5.39 [2.35, 8.44]	24.03 [19.92, 28.14]	<0.0001
Attack 3	188	20 (10.6) 9 (4.8)	911	262 (28.8) 23 (2.5)	3.07 [1.96, 4.80]	2.48 [1.51, 3.46]	16.84 [11.73, 21.95]	<0.0001
Attack 4	171	21 (12.3) 10 (5.8)	860	282 (32.8) 35 (4.1)	3.04 [1.97, 4.67]	2.38 [1.51, 3.25]	18.65 [13.05, 24.25]	<0.0001
Overall effect	1165	132 (11.3) 41 (3.5)	3344	981 (29.3) 113 (3.4)	3.56 [2.86, 4.43]	2.83 [2.28, 3.38]	18.47 [16.11, 20.82]	<0.0001
Interaction								0.0174

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.1.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN FREEDOM, 4 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%)	N	n (%)	OR	RR	RD	p-value
Attack		k (%)		k (%)	[95% CI]	[95% CI]	[95% CI]	
Attack 1	612	156 (25.5)	602	319 (53.0)	3.63	2.22	29.47	<0.0001
		38 (6.2)		40 (6.6)	[2.85, 4.61]	[1.87, 2.56]	[24.32, 34.61]	
Attack 2	194	42 (21.6)	971	570 (58.7)	5.10	2.70	36.84	<0.0001
		18 (9.3)		60 (6.2)	[3.58, 7.27]	[1.98, 3.42]	[30.45, 43.24]	
Attack 3	188	47 (25.0)	911	495 (54.3)	3.34	2.08	27.96	<0.0001
		9 (4.8)		71 (7.8)	[2.37, 4.69]	[1.57, 2.58]	[21.10, 34.81]	
Attack 4	171	41 (24.0)	860	497 (57.8)	3.96	2.25	32.04	<0.0001
		12 (7.0)		64 (7.4)	[2.79, 5.62]	[1.69, 2.82]	[25.09, 38.98]	
Overall effect	1165	286 (24.5)	3344	1881 (56.3)	3.95	2.30	31.63	<0.0001
		77 (6.6)		235 (7.0)	[3.39, 4.61]	[2.04, 2.56]	[28.60, 34.65]	
Interaction								0.3521

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.1.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN FREEDOM, 8 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	315 (51.5) 84 (13.7)	602	403 (66.9) 80 (13.3)	2.12 [1.68, 2.67]	1.36 [1.23, 1.48]	17.89 [12.52, 23.26]	<0.0001
Attack 2	194	95 (49.0) 37 (19.1)	971	687 (70.8) 150 (15.4)	2.41 [1.79, 3.26]	1.41 [1.22, 1.61]	20.69 [13.43, 27.94]	<0.0001
Attack 3	188	91 (48.4) 21 (11.2)	911	658 (72.2) 124 (13.6)	2.49 [1.83, 3.39]	1.42 [1.22, 1.62]	21.24 [13.84, 28.64]	<0.0001
Attack 4	171	85 (49.7) 25 (14.6)	860	612 (71.2) 135 (15.7)	2.44 [1.77, 3.36]	1.42 [1.21, 1.63]	20.90 [13.16, 28.65]	<0.0001
Overall effect	1165	586 (50.3) 167 (14.3)	3344	2360 (70.6) 489 (14.6)	2.36 [2.06, 2.71]	1.40 [1.31, 1.49]	20.20 [16.89, 23.51]	<0.0001
Interaction								0.8166

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.1.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF PAIN FREEDOM, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	409 (66.8) 47 (7.7)	602	489 (81.2) 43 (7.1)	2.36 [1.83, 3.05]	1.24 [1.16, 1.32]	16.07 [11.46, 20.68]	<0.0001
Attack 2	194	135 (69.6) 19 (9.8)	971	777 (80.0) 77 (7.9)	1.70 [1.22, 2.37]	1.14 [1.03, 1.25]	9.84 [3.21, 16.48]	0.0017
Attack 3	188	109 (58.0) 21 (11.2)	911	755 (82.9) 55 (6.0)	3.21 [2.34, 4.41]	1.39 [1.23, 1.54]	22.98 [16.00, 29.96]	<0.0001
Attack 4	171	112 (65.5) 18 (10.5)	860	714 (83.0) 56 (6.5)	2.59 [1.83, 3.66]	1.27 [1.13, 1.40]	17.56 [10.37, 24.75]	<0.0001
Overall effect	1165	765 (65.7) 105 (9.0)	3344	2735 (81.8) 231 (6.9)	2.40 [2.07, 2.79]	1.25 [1.20, 1.31]	16.55 [13.50, 19.60]	<0.0001
Interaction								0.0615

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.1.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN FREEDOM, 48 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	437 (71.4) 72 (11.8)	602	485 (80.6) 85 (14.1)	1.70 [1.31, 2.20]	1.13 [1.06, 1.20]	9.55 [4.95, 14.14]	<0.0001
Attack 2	194	143 (73.7) 26 (13.4)	971	779 (80.2) 119 (12.3)	1.45 [1.04, 2.02]	1.09 [1.00, 1.18]	6.58 [0.32, 12.84]	0.0287
Attack 3	188	139 (73.9) 26 (13.8)	911	741 (81.3) 102 (11.2)	1.36 [0.97, 1.90]	1.07 [0.99, 1.16]	5.32 [-0.75, 11.38]	0.0706
Attack 4	171	119 (69.6) 30 (17.5)	860	659 (76.6) 135 (15.7)	1.46 [1.04, 2.06]	1.11 [1.00, 1.22]	7.51 [0.34, 14.68]	0.0309
Overall effect	1165	838 (71.9) 154 (13.2)	3344	2664 (79.7) 441 (13.2)	1.49 [1.28, 1.73]	1.10 [1.06, 1.14]	7.23 [4.37, 10.10]	<0.0001
Interaction								0.7579

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.2.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN FREEDOM, FROM 2 TO 24 HOURS

mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%)	N	n (%)	OR	RR	RD	p-value
Attack		k (%)		k (%)	[95% CI]	[95% CI]	[95% CI]	
Attack 1	612	39 (6.4)	602	108 (17.9)	3.64	3.16	12.40	<0.0001
		306 (50.0)		198 (32.9)	[2.48, 5.34]	[2.06, 4.26]	[8.92, 15.88]	
Attack 2	194	7 (3.6)	971	230 (23.7)	8.81	6.99	19.94	<0.0001
		114 (58.8)		313 (32.2)	[4.07, 19.05]	[1.81, 12.17]	[16.37, 23.51]	
Attack 3	188	15 (8.0)	911	212 (23.3)	2.96	2.52	13.57	<0.0001
		112 (59.6)		294 (32.3)	[1.80, 4.87]	[1.40, 3.65]	[8.94, 18.19]	
Attack 4	171	14 (8.2)	860	228 (26.5)	3.44	2.81	16.56	<0.0001
		105 (61.4)		275 (32.0)	[2.07, 5.73]	[1.53, 4.10]	[11.66, 21.47]	
Overall effect	1165	75 (6.4)	3344	778 (23.3)	4.25	3.53	15.96	<0.0001
		637 (54.7)		1080 (32.3)	[3.25, 5.56]	[2.64, 4.41]	[13.91, 18.00]	
Interaction								0.1318

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.2.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN FREEDOM, FROM 4 TO 24 HOURS

mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	85 (13.9) 320 (52.3)	602	224 (37.2) 214 (35.5)	4.08 [3.08, 5.39]	2.92 [2.26, 3.57]	24.75 [20.16, 29.35]	<0.0001
Attack 2	194	14 (7.2) 121 (62.4)	971	417 (42.9) 343 (35.3)	9.12 [5.31, 15.67]	5.68 [2.88, 8.47]	34.96 [30.18, 39.73]	<0.0001
Attack 3	188	29 (15.4) 115 (61.2)	911	382 (41.9) 332 (36.4)	3.68 [2.46, 5.50]	2.57 [1.73, 3.42]	25.29 [19.28, 31.30]	<0.0001
Attack 4	171	24 (14.0) 108 (63.2)	860	390 (45.3) 303 (35.2)	4.51 [2.98, 6.83]	2.94 [1.93, 3.94]	29.58 [23.58, 35.59]	<0.0001
Overall effect	1165	152 (13.0) 664 (57.0)	3344	1413 (42.3) 1192 (35.6)	4.99 [4.07, 6.10]	3.33 [2.75, 3.91]	29.07 [26.44, 31.71]	<0.0001
Interaction								0.0472

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.2.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN FREEDOM, FROM 2 TO 48 HOURS

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	35 (5.7) 328 (53.6)	602	100 (16.6) 227 (37.7)	3.62 [2.43, 5.39]	3.19 [2.02, 4.35]	11.44 [8.10, 14.78]	<0.0001
Attack 2	194	5 (2.6) 121 (62.4)	971	213 (21.9) 359 (37.0)	12.33 [4.77, 31.87]	9.88 [0.75, 19.02]	19.42 [16.16, 22.67]	<0.0001
Attack 3	188	13 (6.9) 118 (62.8)	911	191 (21.0) 336 (36.9)	2.97 [1.76, 5.02]	2.57 [1.34, 3.81]	12.33 [7.94, 16.72]	<0.0001
Attack 4	171	11 (6.4) 109 (63.7)	860	194 (22.6) 334 (38.8)	3.77 [2.11, 6.76]	3.17 [1.47, 4.86]	14.98 [10.49, 19.46]	<0.0001
Overall effect	1165	64 (5.5) 676 (58.0)	3344	698 (20.9) 1256 (37.6)	4.73 [3.46, 6.47]	3.98 [2.81, 5.16]	14.98 [13.03, 16.93]	<0.0001
Interaction								0.0831

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.2.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN FREEDOM, FROM 4 TO 48 HOURS

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	70 (11.4) 340 (55.6)	602	200 (33.2) 240 (39.9)	4.17 [3.10, 5.62]	3.11 [2.34, 3.88]	22.71 [18.32, 27.09]	<0.0001
Attack 2	194	12 (6.2) 128 (66.0)	971	376 (38.7) 384 (39.5)	9.39 [5.20, 16.97]	6.18 [2.80, 9.56]	32.10 [27.56, 36.64]	<0.0001
Attack 3	188	22 (11.7) 121 (64.4)	911	347 (38.1) 372 (40.8)	4.25 [2.73, 6.64]	3.04 [1.88, 4.19]	25.11 [19.58, 30.64]	<0.0001
Attack 4	171	20 (11.7) 112 (65.5)	860	329 (38.3) 357 (41.5)	4.34 [2.75, 6.87]	3.08 [1.87, 4.29]	25.52 [19.86, 31.18]	<0.0001
Overall effect	1165	124 (10.6) 701 (60.2)	3344	1252 (37.4) 1353 (40.5)	5.19 [4.15, 6.48]	3.65 [2.93, 4.37]	26.66 [24.17, 29.15]	<0.0001
Interaction								0.1057

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.3.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN RELIEF, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	334 (54.6) 12 (2.0)	602	435 (72.3) 18 (3.0)	2.35 [1.85, 2.99]	1.36 [1.24, 1.48]	19.50 [14.22, 24.78]	<0.0001
Attack 2	194	85 (43.8) 10 (5.2)	971	711 (73.2) 37 (3.8)	3.49 [2.54, 4.80]	1.66 [1.39, 1.93]	29.23 [21.67, 36.80]	<0.0001
Attack 3	188	84 (44.7) 9 (4.8)	911	656 (72.0) 23 (2.5)	3.12 [2.26, 4.31]	1.59 [1.33, 1.84]	26.73 [19.01, 34.44]	<0.0001
Attack 4	171	75 (43.9) 10 (5.8)	860	622 (72.3) 35 (4.1)	3.31 [2.38, 4.61]	1.63 [1.35, 1.90]	28.07 [20.21, 35.93]	<0.0001
Overall effect	1165	578 (49.6) 41 (3.5)	3344	2424 (72.5) 113 (3.4)	3.04 [2.62, 3.51]	1.55 [1.44, 1.66]	25.89 [22.43, 29.36]	<0.0001
Interaction								0.1847

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.3.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF PAIN RELIEF, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	413 (67.5) 38 (6.2)	602	518 (86.0) 40 (6.6)	3.20 [2.41, 4.26]	1.29 [1.21, 1.37]	19.50 [14.96, 24.03]	<0.0001
Attack 2	194	129 (66.5) 18 (9.3)	971	832 (85.7) 60 (6.2)	3.03 [2.14, 4.30]	1.28 [1.15, 1.41]	18.89 [11.96, 25.81]	<0.0001
Attack 3	188	112 (59.6) 9 (4.8)	911	771 (84.6) 71 (7.8)	3.56 [2.52, 5.01]	1.38 [1.22, 1.54]	23.54 [16.25, 30.84]	<0.0001
Attack 4	171	99 (57.9) 12 (7.0)	860	729 (84.8) 64 (7.4)	4.17 [2.92, 5.94]	1.46 [1.27, 1.65]	26.99 [19.28, 34.70]	<0.0001
Overall effect	1165	753 (64.6) 77 (6.6)	3344	2850 (85.2) 235 (7.0)	3.46 [2.95, 4.07]	1.35 [1.28, 1.41]	22.16 [18.92, 25.40]	<0.0001
Interaction								0.5927

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.
 CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.3.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN RELIEF, 8 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	472 (77.1) 84 (13.7)	602	506 (84.1) 80 (13.3)	1.71 [1.29, 2.26]	1.11 [1.05, 1.16]	8.12 [3.92, 12.32]	0.0002
Attack 2	194	143 (73.7) 37 (19.1)	971	805 (82.9) 150 (15.4)	1.63 [1.15, 2.30]	1.11 [1.02, 1.20]	7.96 [1.82, 14.10]	0.0057
Attack 3	188	145 (77.1) 21 (11.2)	911	767 (84.2) 124 (13.6)	1.45 [1.00, 2.10]	1.07 [0.99, 1.15]	5.59 [-0.43, 11.60]	0.0509
Attack 4	171	126 (73.7) 25 (14.6)	860	706 (82.1) 135 (15.7)	1.59 [1.09, 2.30]	1.10 [1.01, 1.20]	7.79 [1.01, 14.56]	0.0149
Overall effect	1165	886 (76.1) 167 (14.3)	3344	2784 (83.3) 489 (14.6)	1.59 [1.35, 1.87]	1.10 [1.06, 1.14]	7.36 [4.60, 10.11]	<0.0001
Interaction								0.9250

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.3.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN RELIEF, 24 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	525 (85.8) 47 (7.7)	602	550 (91.4) 43 (7.1)	1.93 [1.37, 2.72]	1.07 [1.03, 1.11]	6.34 [3.09, 9.59]	0.0002
Attack 2	194	160 (82.5) 19 (9.8)	971	880 (90.6) 77 (7.9)	2.09 [1.41, 3.10]	1.10 [1.03, 1.17]	8.27 [3.09, 13.44]	0.0003
Attack 3	188	154 (81.9) 21 (11.2)	911	849 (93.2) 55 (6.0)	2.54 [1.69, 3.82]	1.11 [1.05, 1.18]	9.24 [4.35, 14.14]	<0.0001
Attack 4	171	145 (84.8) 18 (10.5)	860	793 (92.2) 56 (6.5)	2.02 [1.32, 3.08]	1.08 [1.02, 1.14]	6.92 [2.00, 11.84]	0.0012
Overall effect	1165	984 (84.5) 105 (9.0)	3344	3072 (91.9) 231 (6.9)	2.13 [1.77, 2.56]	1.09 [1.06, 1.12]	7.68 [5.54, 9.82]	<0.0001
Interaction								0.7918

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.3.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PAIN RELIEF, 48 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	513 (83.8) 72 (11.8)	602	511 (84.9) 85 (14.1)	1.13 [0.84, 1.52]	1.02 [0.97, 1.07]	1.61 [-2.22, 5.44]	0.4105
Attack 2	194	160 (82.5) 26 (13.4)	971	834 (85.9) 119 (12.3)	1.30 [0.89, 1.90]	1.04 [0.97, 1.11]	3.49 [-1.88, 8.86]	0.1782
Attack 3	188	153 (81.4) 26 (13.8)	911	798 (87.6) 102 (11.2)	1.35 [0.92, 1.97]	1.05 [0.98, 1.11]	3.89 [-1.34, 9.12]	0.1202
Attack 4	171	135 (78.9) 30 (17.5)	860	715 (83.1) 135 (15.7)	1.34 [0.92, 1.95]	1.06 [0.97, 1.14]	4.62 [-1.63, 10.87]	0.1260
Overall effect	1165	961 (82.5) 154 (13.2)	3344	2858 (85.5) 441 (13.2)	1.28 [1.08, 1.51]	1.04 [1.01, 1.07]	3.37 [0.97, 5.76]	0.0041
Interaction								0.8704

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.4.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN RELIEF, FROM 2 TO 24 HOURS

mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	222 (36.3) 306 (50.0)	602	366 (60.8) 198 (32.9)	2.99 [2.37, 3.77]	1.77 [1.55, 1.99]	26.69 [21.32, 32.06]	<0.0001
Attack 2	194	53 (27.3) 114 (58.8)	971	609 (62.7) 313 (32.2)	4.57 [3.24, 6.44]	2.33 [1.78, 2.88]	35.79 [28.83, 42.74]	<0.0001
Attack 3	188	53 (28.2) 112 (59.6)	911	571 (62.7) 294 (32.3)	4.19 [2.98, 5.89]	2.19 [1.69, 2.69]	34.07 [26.96, 41.18]	<0.0001
Attack 4	171	50 (29.2) 105 (61.4)	860	555 (64.5) 275 (32.0)	4.33 [3.07, 6.11]	2.17 [1.68, 2.67]	34.98 [27.69, 42.27]	<0.0001
Overall effect	1165	378 (32.4) 637 (54.7)	3344	2101 (62.8) 1080 (32.3)	3.97 [3.41, 4.62]	2.10 [1.89, 2.31]	32.97 [29.69, 36.24]	<0.0001
Interaction								0.1249

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.4.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN RELIEF, FROM 4 TO 24 HOURS

mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	219 (35.8) 320 (52.3)	602	354 (58.8) 214 (35.5)	2.78 [2.20, 3.50]	1.72 [1.50, 1.94]	24.90 [19.49, 30.30]	<0.0001
Attack 2	194	49 (25.3) 121 (62.4)	971	583 (60.0) 343 (35.3)	4.54 [3.19, 6.44]	2.42 [1.81, 3.02]	35.13 [28.30, 41.96]	<0.0001
Attack 3	188	52 (27.7) 115 (61.2)	911	542 (59.5) 332 (36.4)	3.72 [2.65, 5.23]	2.11 [1.62, 2.59]	31.18 [24.10, 38.25]	<0.0001
Attack 4	171	49 (28.7) 108 (63.2)	860	529 (61.5) 303 (35.2)	3.90 [2.76, 5.50]	2.11 [1.62, 2.60]	32.43 [25.16, 39.70]	<0.0001
Overall effect	1165	369 (31.7) 664 (57.0)	3344	2008 (60.0) 1192 (35.6)	3.68 [3.15, 4.29]	2.07 [1.86, 2.28]	31.03 [27.76, 34.30]	<0.0001
Interaction								0.1047

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.4.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN RELIEF, FROM 2 TO 48 HOURS

MITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	196 (32.0) 328 (53.6)	602	330 (54.8) 227 (37.7)	2.76 [2.19, 3.48]	1.79 [1.54, 2.03]	24.34 [19.01, 29.68]	<0.0001
Attack 2	194	42 (21.6) 121 (62.4)	971	549 (56.5) 359 (37.0)	4.88 [3.38, 7.05]	2.69 [1.94, 3.44]	35.45 [28.94, 41.96]	<0.0001
Attack 3	188	42 (22.3) 118 (62.8)	911	521 (57.2) 336 (36.9)	4.43 [3.09, 6.35]	2.48 [1.82, 3.14]	33.90 [27.16, 40.65]	<0.0001
Attack 4	171	44 (25.7) 109 (63.7)	860	484 (56.3) 334 (38.8)	3.75 [2.62, 5.38]	2.20 [1.64, 2.77]	30.73 [23.59, 37.87]	<0.0001
Overall effect	1165	324 (27.8) 676 (58.0)	3344	1884 (56.3) 1256 (37.6)	3.87 [3.29, 4.54]	2.26 [2.00, 2.52]	31.28 [28.09, 34.47]	<0.0001
Interaction								0.0348

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.4.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF SUSTAINED PAIN RELIEF, FROM 4 TO 48 HOURS

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	196 (32.0) 340 (55.6)	602	321 (53.3) 240 (39.9)	2.58 [2.05, 3.26]	1.73 [1.49, 1.97]	22.69 [17.33, 28.05]	<0.0001
Attack 2	194	39 (20.1) 128 (66.0)	971	528 (54.4) 384 (39.5)	4.87 [3.35, 7.10]	2.78 [1.97, 3.58]	34.65 [28.27, 41.03]	<0.0001
Attack 3	188	41 (21.8) 121 (64.4)	911	495 (54.3) 372 (40.8)	4.06 [2.82, 5.84]	2.41 [1.76, 3.06]	31.54 [24.84, 38.24]	<0.0001
Attack 4	171	42 (24.6) 112 (65.5)	860	465 (54.1) 357 (41.5)	3.64 [2.53, 5.25]	2.22 [1.63, 2.80]	29.60 [22.54, 36.67]	<0.0001
Overall effect	1165	318 (27.3) 701 (60.2)	3344	1809 (54.1) 1353 (40.5)	3.69 [3.14, 4.35]	2.24 [1.98, 2.51]	29.86 [26.68, 33.03]	<0.0001
Interaction								0.0219

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.5.1

ATOGEPA^{NT} (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF THE MBS, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	200 (32.7) 12 (2.0)	602	264 (43.9) 18 (3.0)	1.79 [1.42, 2.26]	1.44 [1.23, 1.65]	13.46 [8.16, 18.76]	<0.0001
Attack 2	194	44 (22.7) 10 (5.2)	971	449 (46.2) 37 (3.8)	3.09 [2.17, 4.41]	2.12 [1.55, 2.69]	24.51 [18.06, 30.96]	<0.0001
Attack 3	188	42 (22.3) 9 (4.8)	912	396 (43.4) 23 (2.5)	2.49 [1.76, 3.52]	1.85 [1.38, 2.33]	19.72 [13.23, 26.22]	<0.0001
Attack 4	171	47 (27.5) 10 (5.8)	859	404 (47.0) 34 (4.0)	2.24 [1.59, 3.16]	1.66 [1.27, 2.05]	18.67 [11.50, 25.84]	<0.0001
Overall effect	1165	333 (28.6) 41 (3.5)	3344	1513 (45.2) 112 (3.3)	2.36 [2.03, 2.75]	1.75 [1.56, 1.94]	19.25 [16.17, 22.32]	<0.0001
Interaction								0.0788

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, MBS=Most bothersome symptom, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and MBS at baseline. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.5.2

ATOGEPA^{NT} (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF THE MBS, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	292 (47.7) 38 (6.2)	602	415 (68.9) 40 (6.6)	2.84 [2.24, 3.60]	1.54 [1.39, 1.70]	24.80 [19.43, 30.17]	<0.0001
Attack 2	194	91 (46.9) 18 (9.3)	971	683 (70.3) 60 (6.2)	2.70 [1.99, 3.66]	1.49 [1.27, 1.72]	23.46 [16.14, 30.78]	<0.0001
Attack 3	188	78 (41.5) 9 (4.8)	912	618 (67.8) 71 (7.8)	2.65 [1.95, 3.60]	1.53 [1.29, 1.78]	23.53 [16.12, 30.93]	<0.0001
Attack 4	171	74 (43.3) 12 (7.0)	859	594 (69.2) 63 (7.3)	2.81 [2.03, 3.88]	1.55 [1.29, 1.81]	24.69 [16.91, 32.48]	<0.0001
Overall effect	1165	535 (45.9) 77 (6.6)	3344	2310 (69.1) 234 (7.0)	2.75 [2.39, 3.16]	1.53 [1.42, 1.64]	24.14 [20.82, 27.46]	<0.0001
Interaction								0.9854

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, MBS=Most bothersome symptom, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and MBS at baseline. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.5.3

ATOGEPAnt (STUDY M24-305) - (DATE OF DATAcut: 07072025)
 ANALYSIS OF ABSENCE OF THE MBS, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	400 (65.4) 84 (13.7)	602	456 (75.7) 80 (13.3)	1.89 [1.48, 2.41]	1.20 [1.12, 1.29]	13.01 [8.10, 17.92]	<0.0001
Attack 2	194	123 (63.4) 37 (19.1)	971	735 (75.7) 150 (15.4)	1.66 [1.22, 2.26]	1.16 [1.04, 1.27]	10.42 [3.73, 17.10]	0.0012
Attack 3	188	114 (60.6) 21 (11.2)	912	714 (78.3) 125 (13.7)	2.10 [1.53, 2.88]	1.24 [1.11, 1.37]	15.06 [8.14, 21.97]	<0.0001
Attack 4	171	106 (62.0) 25 (14.6)	859	644 (75.0) 134 (15.6)	1.78 [1.28, 2.48]	1.19 [1.06, 1.33]	12.17 [4.79, 19.54]	0.0006
Overall effect	1165	743 (63.8) 167 (14.3)	3344	2549 (76.2) 489 (14.6)	1.85 [1.61, 2.13]	1.20 [1.14, 1.25]	12.68 [9.62, 15.74]	<0.0001
Interaction								0.7723

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, MBS=Most bothersome symptom, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and MBS at baseline. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

TABLE 4.2.5.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF THE MBS, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	476 (77.8) 47 (7.7)	602	517 (85.9) 43 (7.1)	2.04 [1.53, 2.70]	1.13 [1.08, 1.19]	10.27 [6.27, 14.27]	<0.0001
Attack 2	194	153 (78.9) 19 (9.8)	971	827 (85.2) 77 (7.9)	1.39 [0.97, 1.98]	1.06 [0.99, 1.13]	4.59 [-0.79, 9.97]	0.0742
Attack 3	188	137 (72.9) 21 (11.2)	912	800 (87.7) 55 (6.0)	2.44 [1.73, 3.43]	1.18 [1.09, 1.27]	13.28 [7.32, 19.24]	<0.0001
Attack 4	171	130 (76.0) 18 (10.5)	859	746 (86.8) 55 (6.4)	1.87 [1.30, 2.69]	1.12 [1.03, 1.20]	8.96 [3.09, 14.83]	0.0008
Overall effect	1165	896 (76.9) 105 (9.0)	3344	2890 (86.4) 230 (6.9)	1.89 [1.62, 2.22]	1.12 [1.08, 1.15]	9.22 [6.70, 11.73]	<0.0001
Interaction								0.1685

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, MBS=Most bothersome symptom, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and MBS at baseline. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.5.5

ATOGEPA^{NT} (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF THE MBS, 48 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	479 (78.3) 72 (11.8)	602	495 (82.2) 85 (14.1)	1.35 [1.03, 1.77]	1.06 [1.01, 1.12]	4.77 [0.56, 8.99]	0.0274
Attack 2	194	153 (78.9) 26 (13.4)	971	800 (82.4) 119 (12.3)	1.25 [0.88, 1.77]	1.04 [0.97, 1.12]	3.47 [-2.16, 9.11]	0.2070
Attack 3	188	146 (77.7) 26 (13.8)	912	756 (82.9) 102 (11.2)	1.18 [0.83, 1.67]	1.03 [0.96, 1.10]	2.52 [-3.09, 8.13]	0.3636
Attack 4	171	122 (71.3) 30 (17.5)	859	687 (80.0) 134 (15.6)	1.63 [1.15, 2.29]	1.13 [1.02, 1.23]	9.01 [2.19, 15.83]	0.0055
Overall effect	1165	900 (77.3) 154 (13.2)	3344	2738 (81.9) 440 (13.2)	1.34 [1.15, 1.56]	1.06 [1.03, 1.10]	4.81 [2.20, 7.42]	0.0002
Interaction								0.5942

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, MBS=Most bothersome symptom, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and MBS at baseline. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.6.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHOTOPHOBIA, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	256 (41.8) 12 (2.0)	602	310 (51.5) 18 (3.0)	1.76 [1.39, 2.22]	1.34 [1.18, 1.51]	13.97 [8.30, 19.64]	<0.0001
Attack 2	194	64 (33.0) 10 (5.2)	971	505 (52.0) 37 (3.8)	2.71 [1.93, 3.79]	1.76 [1.37, 2.15]	23.93 [16.52, 31.33]	<0.0001
Attack 3	188	63 (33.5) 9 (4.8)	912	468 (51.3) 23 (2.5)	2.12 [1.51, 2.96]	1.52 [1.20, 1.83]	18.30 [10.52, 26.09]	<0.0001
Attack 4	171	63 (36.8) 10 (5.8)	860	471 (54.8) 35 (4.1)	2.29 [1.62, 3.24]	1.55 [1.22, 1.88]	20.35 [12.18, 28.51]	<0.0001
Overall effect	1165	446 (38.3) 41 (3.5)	3345	1754 (52.4) 113 (3.4)	2.19 [1.89, 2.54]	1.53 [1.39, 1.67]	19.21 [15.71, 22.71]	<0.0001
Interaction								0.2194

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.6.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHOTOPHOBIA, 4 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	325 (53.1) 38 (6.2)	602	441 (73.3) 40 (6.6)	2.85 [2.23, 3.64]	1.44 [1.32, 1.57]	23.37 [18.12, 28.62]	<0.0001
Attack 2	194	98 (50.5) 18 (9.3)	971	695 (71.6) 60 (6.2)	2.65 [1.95, 3.60]	1.43 [1.24, 1.63]	22.30 [14.99, 29.61]	<0.0001
Attack 3	188	86 (45.7) 9 (4.8)	912	643 (70.5) 71 (7.8)	2.77 [2.04, 3.76]	1.49 [1.27, 1.71]	23.80 [16.41, 31.18]	<0.0001
Attack 4	171	85 (49.7) 12 (7.0)	860	628 (73.0) 64 (7.4)	2.65 [1.92, 3.65]	1.42 [1.22, 1.62]	22.08 [14.44, 29.72]	<0.0001
Overall effect	1165	594 (51.0) 77 (6.6)	3345	2407 (72.0) 235 (7.0)	2.73 [2.37, 3.14]	1.45 [1.36, 1.54]	22.91 [19.63, 26.19]	<0.0001
Interaction								0.9812

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.6.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHOTOPHOBIA, 8 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	414 (67.6) 84 (13.7)	602	470 (78.1) 80 (13.3)	1.87 [1.46, 2.40]	1.18 [1.10, 1.26]	12.05 [7.31, 16.78]	<0.0001
Attack 2	194	124 (63.9) 37 (19.1)	971	738 (76.0) 150 (15.4)	1.69 [1.24, 2.30]	1.16 [1.04, 1.28]	10.59 [3.88, 17.31]	0.0010
Attack 3	188	124 (66.0) 21 (11.2)	912	716 (78.5) 125 (13.7)	1.76 [1.28, 2.44]	1.16 [1.05, 1.27]	10.92 [4.23, 17.61]	0.0006
Attack 4	171	112 (65.5) 25 (14.6)	860	652 (75.8) 135 (15.7)	1.59 [1.13, 2.23]	1.14 [1.02, 1.26]	9.36 [2.12, 16.60]	0.0074
Overall effect	1165	774 (66.4) 167 (14.3)	3345	2576 (77.0) 490 (14.6)	1.72 [1.49, 1.99]	1.16 [1.11, 1.21]	10.76 [7.75, 13.77]	<0.0001
Interaction								0.8919

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.6.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHOTOPHOBIA, 24 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	489 (79.9) 47 (7.7)	602	527 (87.5) 43 (7.1)	1.97 [1.47, 2.65]	1.11 [1.06, 1.16]	8.91 [5.14, 12.69]	<0.0001
Attack 2	194	154 (79.4) 19 (9.8)	971	835 (86.0) 77 (7.9)	1.63 [1.14, 2.32]	1.09 [1.01, 1.16]	6.79 [1.37, 12.21]	0.0069
Attack 3	188	138 (73.4) 21 (11.2)	912	804 (88.2) 55 (6.0)	2.33 [1.67, 3.25]	1.16 [1.08, 1.25]	12.18 [6.62, 17.74]	<0.0001
Attack 4	171	133 (77.8) 18 (10.5)	860	756 (87.9) 56 (6.5)	1.87 [1.29, 2.72]	1.11 [1.03, 1.19]	8.48 [2.76, 14.20]	0.0010
Overall effect	1165	914 (78.5) 105 (9.0)	3345	2922 (87.4) 231 (6.9)	1.94 [1.65, 2.27]	1.12 [1.08, 1.15]	9.07 [6.66, 11.48]	<0.0001
Interaction								0.5553

The MITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, MITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.6.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHOTOPHOBIA, 48 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	489 (79.9) 72 (11.8)	602	500 (83.1) 85 (14.1)	1.29 [0.98, 1.70]	1.05 [0.99, 1.10]	3.80 [-0.32, 7.93]	0.0717
Attack 2	194	153 (78.9) 26 (13.4)	971	805 (82.9) 119 (12.3)	1.32 [0.94, 1.86]	1.06 [0.98, 1.13]	4.34 [-1.24, 9.91]	0.1080
Attack 3	188	151 (80.3) 26 (13.8)	912	766 (84.0) 102 (11.2)	1.07 [0.75, 1.52]	1.01 [0.95, 1.08]	0.99 [-4.19, 6.18]	0.7041
Attack 4	171	124 (72.5) 30 (17.5)	860	695 (80.8) 135 (15.7)	1.60 [1.13, 2.26]	1.12 [1.01, 1.22]	8.43 [1.69, 15.18]	0.0085
Overall effect	1165	917 (78.7) 154 (13.2)	3345	2766 (82.7) 441 (13.2)	1.31 [1.12, 1.52]	1.05 [1.02, 1.09]	4.21 [1.69, 6.73]	0.0007
Interaction								0.4862

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.7.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHONOPHOBIA, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	300 (49.0) 12 (2.0)	602	365 (60.6) 18 (3.0)	1.99 [1.57, 2.51]	1.34 [1.20, 1.48]	16.64 [11.05, 22.22]	<0.0001
Attack 2	194	70 (36.1) 10 (5.2)	971	597 (61.5) 37 (3.8)	3.34 [2.37, 4.69]	1.81 [1.44, 2.18]	29.23 [21.44, 37.03]	<0.0001
Attack 3	188	72 (38.3) 9 (4.8)	912	519 (56.9) 23 (2.5)	2.27 [1.64, 3.16]	1.51 [1.23, 1.79]	20.25 [12.42, 28.09]	<0.0001
Attack 4	171	77 (45.0) 10 (5.8)	860	525 (61.0) 35 (4.1)	2.18 [1.55, 3.05]	1.41 [1.17, 1.65]	18.92 [10.65, 27.19]	<0.0001
Overall effect	1165	519 (44.5) 41 (3.5)	3345	2006 (60.0) 113 (3.4)	2.39 [2.06, 2.78]	1.50 [1.38, 1.62]	21.37 [17.79, 24.96]	<0.0001
Interaction								0.1146

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.7.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHONOPHOBIA, 4 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	371 (60.6) 38 (6.2)	602	460 (76.4) 40 (6.6)	2.43 [1.89, 3.13]	1.30 [1.20, 1.40]	18.25 [13.22, 23.29]	<0.0001
Attack 2	194	108 (55.7) 18 (9.3)	971	747 (76.9) 60 (6.2)	2.71 [1.98, 3.71]	1.36 [1.20, 1.53]	20.92 [13.73, 28.11]	<0.0001
Attack 3	188	102 (54.3) 9 (4.8)	912	688 (75.4) 71 (7.8)	2.47 [1.81, 3.38]	1.34 [1.17, 1.50]	19.43 [12.20, 26.65]	<0.0001
Attack 4	171	89 (52.0) 12 (7.0)	860	656 (76.3) 64 (7.4)	3.31 [2.39, 4.59]	1.49 [1.28, 1.70]	25.96 [18.31, 33.61]	<0.0001
Overall effect	1165	670 (57.5) 77 (6.6)	3345	2551 (76.3) 235 (7.0)	2.71 [2.35, 3.13]	1.37 [1.29, 1.44]	21.13 [17.89, 24.37]	<0.0001
Interaction								0.4953

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.7.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHONOPHOBIA, 8 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	427 (69.8) 84 (13.7)	602	478 (79.4) 80 (13.3)	1.87 [1.45, 2.42]	1.17 [1.09, 1.24]	11.57 [6.92, 16.23]	<0.0001
Attack 2	194	130 (67.0) 37 (19.1)	971	755 (77.8) 150 (15.4)	1.56 [1.13, 2.14]	1.12 [1.02, 1.22]	8.49 [2.01, 14.97]	0.0063
Attack 3	188	138 (73.4) 21 (11.2)	912	730 (80.0) 125 (13.7)	1.26 [0.90, 1.77]	1.05 [0.97, 1.13]	3.95 [-2.07, 9.97]	0.1807
Attack 4	171	117 (68.4) 25 (14.6)	860	667 (77.6) 135 (15.7)	1.66 [1.18, 2.32]	1.14 [1.03, 1.26]	9.79 [2.75, 16.82]	0.0036
Overall effect	1165	812 (69.7) 167 (14.3)	3345	2630 (78.6) 490 (14.6)	1.57 [1.36, 1.82]	1.12 [1.07, 1.16]	8.37 [5.48, 11.25]	<0.0001
Interaction								0.3585

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.7.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHONOPHOBIA, 24 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	497 (81.2) 47 (7.7)	602	525 (87.2) 43 (7.1)	1.79 [1.33, 2.39]	1.09 [1.04, 1.14]	7.41 [3.72, 11.10]	0.0001
Attack 2	194	156 (80.4) 19 (9.8)	971	846 (87.1) 77 (7.9)	1.60 [1.11, 2.30]	1.07 [1.01, 1.14]	6.07 [0.81, 11.34]	0.0127
Attack 3	188	148 (78.7) 21 (11.2)	912	817 (89.6) 55 (6.0)	1.92 [1.33, 2.77]	1.10 [1.03, 1.17]	7.93 [2.81, 13.05]	0.0005
Attack 4	171	136 (79.5) 18 (10.5)	860	761 (88.5) 56 (6.5)	1.91 [1.31, 2.78]	1.10 [1.03, 1.18]	8.29 [2.77, 13.81]	0.0008
Overall effect	1165	937 (80.4) 105 (9.0)	3345	2949 (88.2) 231 (6.9)	1.80 [1.53, 2.12]	1.09 [1.06, 1.12]	7.44 [5.14, 9.74]	<0.0001
Interaction								0.8948

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.7.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF PHONOPHOBIA, 48 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	499 (81.5) 72 (11.8)	602	499 (82.9) 85 (14.1)	1.16 [0.88, 1.53]	1.03 [0.98, 1.08]	2.10 [-1.91, 6.12]	0.3054
Attack 2	194	152 (78.4) 26 (13.4)	971	822 (84.7) 119 (12.3)	1.49 [1.05, 2.11]	1.08 [1.00, 1.15]	5.96 [0.36, 11.57]	0.0245
Attack 3	188	154 (81.9) 26 (13.8)	912	779 (85.4) 102 (11.2)	1.05 [0.72, 1.51]	1.01 [0.95, 1.07]	0.60 [-4.43, 5.64]	0.8126
Attack 4	171	130 (76.0) 30 (17.5)	860	696 (80.9) 135 (15.7)	1.39 [0.98, 1.99]	1.08 [0.98, 1.17]	5.73 [-0.77, 12.23]	0.0678
Overall effect	1165	935 (80.3) 154 (13.2)	3345	2796 (83.6) 441 (13.2)	1.26 [1.08, 1.47]	1.04 [1.01, 1.08]	3.46 [1.00, 5.92]	0.0042
Interaction								0.4899

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.8.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF NAUSEA, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	411 (67.2) 12 (2.0)	602	436 (72.4) 18 (3.0)	1.25 [0.97, 1.61]	1.06 [0.99, 1.13]	4.19 [-0.60, 8.97]	0.0870
Attack 2	194	119 (61.3) 10 (5.2)	971	720 (74.2) 37 (3.8)	2.29 [1.63, 3.22]	1.29 [1.13, 1.45]	17.35 [9.66, 25.05]	<0.0001
Attack 3	188	117 (62.2) 9 (4.8)	912	688 (75.4) 23 (2.5)	1.70 [1.22, 2.37]	1.15 [1.04, 1.27]	10.44 [3.41, 17.46]	0.0019
Attack 4	171	113 (66.1) 10 (5.8)	860	665 (77.3) 35 (4.1)	1.96 [1.37, 2.82]	1.19 [1.06, 1.32]	12.75 [5.24, 20.25]	0.0003
Overall effect	1165	760 (65.2) 41 (3.5)	3345	2509 (75.0) 113 (3.4)	1.76 [1.51, 2.05]	1.16 [1.11, 1.22]	11.07 [7.84, 14.29]	<0.0001
Interaction								0.0365

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.8.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF NAUSEA, 4 HOURS AFTER THE DB DOSE
 MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	440 (71.9) 38 (6.2)	602	499 (82.9) 40 (6.6)	2.00 [1.51, 2.64]	1.15 [1.08, 1.21]	11.00 [6.60, 15.40]	<0.0001
Attack 2	194	143 (73.7) 18 (9.3)	971	823 (84.8) 60 (6.2)	2.12 [1.48, 3.05]	1.16 [1.06, 1.26]	11.70 [5.26, 18.14]	<0.0001
Attack 3	188	130 (69.1) 9 (4.8)	912	766 (84.0) 71 (7.8)	2.20 [1.52, 3.18]	1.18 [1.07, 1.30]	13.10 [6.15, 20.05]	<0.0001
Attack 4	171	122 (71.3) 12 (7.0)	860	731 (85.0) 64 (7.4)	2.25 [1.54, 3.28]	1.18 [1.07, 1.29]	12.91 [5.98, 19.83]	<0.0001
Overall effect	1165	835 (71.7) 77 (6.6)	3345	2819 (84.3) 235 (7.0)	2.14 [1.81, 2.53]	1.17 [1.12, 1.21]	12.17 [9.16, 15.18]	<0.0001
Interaction								0.9608

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.8.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF NAUSEA, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	480 (78.4) 84 (13.7)	602	496 (82.4) 80 (13.3)	1.40 [1.06, 1.84]	1.06 [1.01, 1.12]	5.05 [0.87, 9.24]	0.0185
Attack 2	194	146 (75.3) 37 (19.1)	971	794 (81.8) 150 (15.4)	1.45 [1.02, 2.05]	1.08 [0.99, 1.17]	6.06 [-0.07, 12.19]	0.0386
Attack 3	188	143 (76.1) 21 (11.2)	912	764 (83.8) 125 (13.7)	1.45 [1.01, 2.08]	1.07 [0.99, 1.16]	5.70 [-0.31, 11.71]	0.0465
Attack 4	171	133 (77.8) 25 (14.6)	860	706 (82.1) 135 (15.7)	1.28 [0.86, 1.90]	1.05 [0.96, 1.14]	3.94 [-2.61, 10.49]	0.2161
Overall effect	1165	902 (77.4) 167 (14.3)	3345	2760 (82.5) 490 (14.6)	1.39 [1.18, 1.64]	1.07 [1.03, 1.10]	5.19 [2.47, 7.91]	<0.0001
Interaction								0.9690

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.8.4

ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF NAUSEA, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	534 (87.3) 47 (7.7)	602	543 (90.2) 43 (7.1)	1.52 [1.09, 2.13]	1.05 [1.01, 1.08]	3.97 [0.81, 7.13]	0.0147
Attack 2	194	166 (85.6) 19 (9.8)	971	877 (90.3) 77 (7.9)	1.60 [1.05, 2.44]	1.06 [1.00, 1.12]	4.88 [0.02, 9.74]	0.0282
Attack 3	188	156 (83.0) 21 (11.2)	912	843 (92.4) 55 (6.0)	2.11 [1.40, 3.17]	1.09 [1.03, 1.15]	7.48 [2.68, 12.28]	0.0003
Attack 4	171	145 (84.8) 18 (10.5)	860	793 (92.2) 56 (6.5)	1.81 [1.17, 2.80]	1.07 [1.01, 1.13]	5.76 [0.90, 10.62]	0.0076
Overall effect	1165	1001 (85.9) 105 (9.0)	3345	3056 (91.4) 231 (6.9)	1.75 [1.45, 2.10]	1.06 [1.04, 1.09]	5.51 [3.45, 7.57]	<0.0001
Interaction								0.6720

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.8.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF NAUSEA, 48 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	512 (83.7) 72 (11.8)	602	510 (84.7) 85 (14.1)	1.11 [0.83, 1.49]	1.02 [0.97, 1.06]	1.40 [-2.45, 5.25]	0.4756
Attack 2	194	160 (82.5) 26 (13.4)	971	837 (86.2) 119 (12.3)	1.36 [0.93, 1.98]	1.05 [0.98, 1.12]	4.05 [-1.29, 9.38]	0.1126
Attack 3	188	153 (81.4) 26 (13.8)	912	795 (87.2) 102 (11.2)	1.30 [0.90, 1.89]	1.04 [0.98, 1.11]	3.47 [-1.71, 8.65]	0.1649
Attack 4	171	135 (78.9) 30 (17.5)	860	717 (83.4) 135 (15.7)	1.36 [0.93, 1.99]	1.06 [0.98, 1.15]	4.82 [-1.48, 11.11]	0.1118
Overall effect	1165	960 (82.4) 154 (13.2)	3345	2859 (85.5) 441 (13.2)	1.28 [1.08, 1.51]	1.04 [1.01, 1.07]	3.39 [1.00, 5.78]	0.0038
Interaction								0.8147

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.9.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF VOMITING, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	612	583 (95.3) 12 (2.0)	602	572 (95.0) 18 (3.0)	0.93 [0.55, 1.56]	1.00 [0.98, 1.02]	-0.29 [-2.29, 1.70]	0.7743
Attack 2	194	177 (91.2) 10 (5.2)	971	913 (94.0) 37 (3.8)	1.59 [0.91, 2.79]	1.03 [0.99, 1.07]	2.79 [-1.05, 6.63]	0.1063
Attack 3	188	170 (90.4) 9 (4.8)	912	868 (95.2) 23 (2.5)	2.15 [1.22, 3.76]	1.05 [1.00, 1.09]	4.25 [0.44, 8.06]	0.0077
Attack 4	171	154 (90.1) 10 (5.8)	860	816 (94.9) 35 (4.1)	2.31 [1.28, 4.15]	1.06 [1.00, 1.11]	5.10 [0.65, 9.55]	0.0053
Overall effect	1165	1084 (93.0) 41 (3.5)	3345	3169 (94.7) 113 (3.4)	1.64 [1.26, 2.15]	1.03 [1.01, 1.05]	2.62 [1.03, 4.22]	0.0003
Interaction								0.0923

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.9.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF VOMITING, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	556 (90.8) 38 (6.2)	602	560 (93.0) 40 (6.6)	1.37 [0.91, 2.07]	1.02 [0.99, 1.06]	2.21 [-0.66, 5.08]	0.1338
Attack 2	194	170 (87.6) 18 (9.3)	971	902 (92.9) 60 (6.2)	1.82 [1.12, 2.96]	1.06 [1.00, 1.11]	4.96 [0.30, 9.62]	0.0157
Attack 3	188	171 (91.0) 9 (4.8)	912	837 (91.8) 71 (7.8)	1.09 [0.64, 1.87]	1.01 [0.96, 1.05]	0.67 [-3.47, 4.81]	0.7463
Attack 4	171	151 (88.3) 12 (7.0)	860	792 (92.1) 64 (7.4)	1.55 [0.93, 2.59]	1.04 [0.99, 1.10]	3.79 [-1.10, 8.68]	0.0896
Overall effect	1165	1048 (90.0) 77 (6.6)	3345	3091 (92.4) 235 (7.0)	1.43 [1.14, 1.81]	1.03 [1.01, 1.05]	2.83 [0.85, 4.80]	0.0024
Interaction								0.5684

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.9.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ABSENCE OF VOMITING, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	522 (85.3) 84 (13.7)	602	521 (86.5) 80 (13.3)	1.19 [0.88, 1.62]	1.02 [0.98, 1.07]	2.06 [-1.54, 5.66]	0.2631
Attack 2	194	155 (79.9) 37 (19.1)	971	818 (84.2) 150 (15.4)	1.29 [0.89, 1.87]	1.04 [0.97, 1.12]	3.63 [-1.95, 9.22]	0.1792
Attack 3	188	163 (86.7) 21 (11.2)	912	787 (86.3) 125 (13.7)	0.91 [0.59, 1.41]	0.99 [0.93, 1.04]	-1.09 [-6.02, 3.84]	0.6732
Attack 4	171	144 (84.2) 25 (14.6)	860	725 (84.3) 135 (15.7)	0.96 [0.62, 1.48]	0.99 [0.93, 1.06]	-0.56 [-6.20, 5.09]	0.8483
Overall effect	1165	984 (84.5) 167 (14.3)	3345	2851 (85.2) 490 (14.6)	1.08 [0.90, 1.29]	1.01 [0.98, 1.04]	0.92 [-1.43, 3.28]	0.4343
Interaction								0.5746

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.9.4

ATOGEPA^{NT} (STUDY M24-305) - (DATE OF DATA^{CUT}: 07072025)

ANALYSIS OF ABSENCE OF VOMITING, 24 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	560 (91.5) 47 (7.7)	602	558 (92.7) 43 (7.1)	1.31 [0.90, 1.91]	1.02 [0.99, 1.05]	1.94 [-0.72, 4.60]	0.1546
Attack 2	194	173 (89.2) 19 (9.8)	971	892 (91.9) 77 (7.9)	1.48 [0.95, 2.30]	1.04 [0.99, 1.09]	3.43 [-0.84, 7.70]	0.0828
Attack 3	188	165 (87.8) 21 (11.2)	912	857 (94.0) 55 (6.0)	1.70 [1.10, 2.65]	1.05 [1.00, 1.09]	4.24 [0.24, 8.24]	0.0180
Attack 4	171	151 (88.3) 18 (10.5)	860	804 (93.5) 56 (6.5)	1.70 [1.07, 2.69]	1.05 [1.00, 1.10]	4.42 [0.05, 8.79]	0.0239
Overall effect	1165	1049 (90.0) 105 (9.0)	3345	3111 (93.0) 231 (6.9)	1.54 [1.26, 1.88]	1.04 [1.02, 1.06]	3.46 [1.72, 5.21]	<0.0001
Interaction								0.7978

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.9.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ABSENCE OF VOMITING, 48 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	535 (87.4) 72 (11.8)	602	517 (85.9) 85 (14.1)	0.92 [0.67, 1.25]	0.99 [0.95, 1.03]	-0.98 [-4.51, 2.55]	0.5853
Attack 2	194	167 (86.1) 26 (13.4)	971	849 (87.4) 119 (12.3)	1.13 [0.75, 1.69]	1.02 [0.96, 1.07]	1.40 [-3.40, 6.19]	0.5568
Attack 3	188	161 (85.6) 26 (13.8)	912	810 (88.8) 102 (11.2)	1.08 [0.72, 1.63]	1.01 [0.96, 1.06]	0.87 [-3.76, 5.50]	0.7060
Attack 4	171	141 (82.5) 30 (17.5)	860	724 (84.2) 135 (15.7)	1.17 [0.79, 1.74]	1.03 [0.95, 1.10]	2.26 [-3.62, 8.15]	0.4364
Overall effect	1165	1004 (86.2) 154 (13.2)	3345	2900 (86.7) 441 (13.2)	1.07 [0.90, 1.28]	1.01 [0.98, 1.04]	0.82 [-1.35, 2.98]	0.4538
Interaction								0.7813

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naive), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), and baseline presence of symptom (yes/no). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.10.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF RESCUE MEDICATION USE, WITHIN 24 HOURS

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	327 (53.3) 0 (0.0)	602	91 (15.1) 0 (0.0)	0.14 [0.11, 0.19]	0.27 [0.21, 0.32]	-39.04 [-43.98, -34.10]	<0.0001
Attack 2	194	110 (56.7) 0 (0.0)	971	178 (18.3) 0 (0.0)	0.16 [0.11, 0.22]	0.30 [0.24, 0.36]	-39.90 [-47.40, -32.41]	<0.0001
Attack 3	188	106 (56.4) 0 (0.0)	912	150 (16.4) 0 (0.0)	0.14 [0.10, 0.20]	0.27 [0.22, 0.32]	-41.33 [-48.99, -33.67]	<0.0001
Attack 4	171	95 (55.6) 0 (0.0)	860	133 (15.5) 0 (0.0)	0.14 [0.10, 0.20]	0.26 [0.20, 0.32]	-40.31 [-48.25, -32.37]	<0.0001
Overall effect	1166	638 (54.7) 0 (0.0)	3345	552 (16.5) 0 (0.0)	0.14 [0.12, 0.17]	0.27 [0.25, 0.30]	-40.19 [-43.65, -36.72]	<0.0001
Interaction								0.9595

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.2.11.1.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PGI-C MUCH BETTER OR VERY MUCH BETTER, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	131 (21.4) 12 (2.0)	602	241 (40.0) 18 (3.0)	2.52 [1.97, 3.24]	1.91 [1.57, 2.25]	19.17 [14.18, 24.17]	<0.0001
Attack 2	194	19 (9.8) 10 (5.2)	971	401 (41.3) 37 (3.8)	7.13 [4.35, 11.69]	4.59 [2.56, 6.61]	32.45 [27.49, 37.41]	<0.0001
Attack 3	188	33 (17.6) 9 (4.8)	912	373 (40.9) 23 (2.5)	3.07 [2.09, 4.49]	2.23 [1.55, 2.90]	22.36 [16.18, 28.54]	<0.0001
Attack 4	171	32 (18.7) 10 (5.8)	860	384 (44.7) 36 (4.2)	3.19 [2.19, 4.64]	2.22 [1.57, 2.87]	24.26 [17.84, 30.68]	<0.0001
Overall effect	1165	215 (18.5) 41 (3.5)	3345	1399 (41.8) 114 (3.4)	3.64 [3.03, 4.38]	2.54 [2.16, 2.93]	25.24 [22.41, 28.07]	<0.0001
Interaction								0.0045

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, PGI-C=Patient Global Impression of Change, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.11.2.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PGI-C ANY IMPROVEMENT, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	357 (58.3) 12 (2.0)	602	469 (77.9) 18 (3.0)	2.55 [1.98, 3.28]	1.34 [1.23, 1.45]	19.78 [14.65, 24.90]	<0.0001
Attack 2	194	91 (46.9) 10 (5.2)	971	730 (75.2) 37 (3.8)	3.53 [2.57, 4.83]	1.62 [1.37, 1.87]	28.90 [21.44, 36.36]	<0.0001
Attack 3	188	94 (50.0) 9 (4.8)	912	697 (76.4) 23 (2.5)	3.14 [2.27, 4.34]	1.51 [1.29, 1.73]	25.66 [17.99, 33.32]	<0.0001
Attack 4	171	92 (53.8) 10 (5.8)	860	659 (76.6) 36 (4.2)	2.84 [2.03, 3.97]	1.43 [1.23, 1.63]	23.02 [15.14, 30.91]	<0.0001
Overall effect	1165	634 (54.4) 41 (3.5)	3345	2555 (76.4) 114 (3.4)	2.99 [2.58, 3.47]	1.47 [1.37, 1.56]	24.34 [20.86, 27.81]	<0.0001
Interaction								0.4477

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, PGI-C=Patient Global Impression of Change, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.11.3.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF PGI-C UNCHANGED OR IMPROVED, 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	526 (85.9) 12 (2.0)	602	557 (92.5) 18 (3.0)	1.99 [1.37, 2.89]	1.07 [1.03, 1.11]	6.23 [2.92, 9.54]	0.0003
Attack 2	194	164 (84.5) 10 (5.2)	971	877 (90.3) 37 (3.8)	1.79 [1.15, 2.78]	1.07 [1.01, 1.14]	6.18 [0.83, 11.54]	0.0099
Attack 3	188	149 (79.3) 9 (4.8)	912	835 (91.6) 23 (2.5)	2.80 [1.83, 4.31]	1.15 [1.06, 1.23]	11.85 [5.83, 17.87]	<0.0001
Attack 4	171	140 (81.9) 10 (5.8)	860	788 (91.6) 36 (4.2)	2.57 [1.64, 4.05]	1.13 [1.04, 1.21]	10.35 [4.32, 16.38]	<0.0001
Overall effect	1165	979 (84.0) 41 (3.5)	3345	3057 (91.4) 114 (3.4)	2.25 [1.83, 2.77]	1.10 [1.07, 1.14]	8.53 [6.01, 11.04]	<0.0001
Interaction								0.4250

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, PGI-C=Patient Global Impression of Change, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.11.4.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF PGI-C ANY WORSENING, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	612	74 (12.1) 12 (2.0)	602	27 (4.5) 18 (3.0)	0.34 [0.22, 0.53]	0.37 [0.21, 0.52]	-6.96 [-9.77, -4.16]	<0.0001
Attack 2	194	20 (10.3) 10 (5.2)	971	57 (5.9) 37 (3.8)	0.53 [0.31, 0.91]	0.56 [0.29, 0.83]	-4.16 [-8.33, 0.02]	0.0217
Attack 3	188	30 (16.0) 9 (4.8)	912	54 (5.9) 23 (2.5)	0.34 [0.21, 0.55]	0.37 [0.21, 0.53]	-9.01 [-14.12, -3.89]	<0.0001
Attack 4	171	21 (12.3) 10 (5.8)	860	36 (4.2) 36 (4.2)	0.30 [0.17, 0.51]	0.32 [0.16, 0.48]	-7.81 [-12.40, -3.21]	<0.0001
Overall effect	1165	145 (12.4) 41 (3.5)	3345	174 (5.2) 114 (3.4)	0.37 [0.29, 0.47]	0.40 [0.31, 0.48]	-6.92 [-9.00, -4.85]	<0.0001
Interaction								0.4509

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, PGI-C=Patient Global Impression of Change, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.2.12.1.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF CFS ABILITY TO THINK CLEARLY (CFS = 0), 2 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	230 (37.5) 14 (2.3)	602	280 (46.5) 21 (3.5)	1.78 [1.37, 2.32]	1.43 [1.19, 1.67]	13.49 [7.39, 19.58]	<0.0001
Attack 2	194	51 (26.3) 11 (5.7)	971	468 (48.2) 41 (4.2)	3.27 [2.22, 4.81]	2.22 [1.56, 2.88]	25.40 [18.54, 32.27]	<0.0001
Attack 3	188	64 (34.0) 10 (5.3)	912	419 (45.9) 27 (3.0)	1.80 [1.25, 2.58]	1.45 [1.09, 1.80]	13.54 [5.66, 21.41]	0.0016
Attack 4	171	60 (35.1) 11 (6.4)	860	422 (49.1) 39 (4.5)	1.84 [1.29, 2.64]	1.43 [1.10, 1.75]	14.74 [6.50, 22.98]	0.0009
Overall effect	1166	405 (34.7) 46 (3.9)	3345	1589 (47.5) 128 (3.8)	2.09 [1.78, 2.47]	1.59 [1.41, 1.77]	17.09 [13.56, 20.63]	<0.0001
Interaction								0.0609

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.12.1.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF CFS ABILITY TO THINK CLEARLY (CFS = 0), 4 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	287 (46.8) 42 (6.9)	602	391 (65.0) 41 (6.8)	2.78 [2.15, 3.59]	1.56 [1.38, 1.74]	24.64 [18.73, 30.55]	<0.0001
Attack 2	194	79 (40.7) 19 (9.8)	971	650 (66.9) 61 (6.3)	3.11 [2.23, 4.32]	1.66 [1.36, 1.97]	27.31 [19.46, 35.17]	<0.0001
Attack 3	188	85 (45.2) 9 (4.8)	912	595 (65.2) 74 (8.1)	2.37 [1.73, 3.26]	1.46 [1.22, 1.70]	20.96 [13.26, 28.65]	<0.0001
Attack 4	171	74 (43.3) 12 (7.0)	860	559 (65.0) 68 (7.9)	2.31 [1.67, 3.21]	1.44 [1.20, 1.67]	20.27 [12.29, 28.25]	<0.0001
Overall effect	1166	525 (45.0) 82 (7.0)	3345	2195 (65.6) 244 (7.3)	2.62 [2.27, 3.04]	1.53 [1.41, 1.64]	23.31 [19.80, 26.83]	<0.0001
Interaction								0.5511

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.12.1.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF CFS ABILITY TO THINK CLEARLY (CFS = 0), 8 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	381 (62.2) 85 (13.9)	602	428 (71.1) 82 (13.6)	1.76 [1.38, 2.25]	1.20 [1.11, 1.30]	12.32 [7.12, 17.51]	<0.0001
Attack 2	194	113 (58.2) 38 (19.6)	971	696 (71.7) 150 (15.4)	1.70 [1.26, 2.29]	1.19 [1.06, 1.33]	11.75 [4.76, 18.75]	0.0006
Attack 3	188	110 (58.5) 21 (11.2)	912	682 (74.8) 125 (13.7)	1.83 [1.35, 2.50]	1.21 [1.08, 1.34]	12.93 [5.96, 19.90]	0.0001
Attack 4	171	105 (61.4) 25 (14.6)	860	632 (73.5) 135 (15.7)	1.65 [1.19, 2.29]	1.17 [1.04, 1.31]	10.79 [3.45, 18.12]	0.0024
Overall effect	1166	709 (60.8) 169 (14.5)	3345	2438 (72.9) 492 (14.7)	1.74 [1.51, 1.99]	1.19 [1.13, 1.25]	11.96 [8.83, 15.09]	<0.0001
Interaction								0.9724

The MITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, k=Number of imputed values, MITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk

Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.12.2.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF CFS IMPROVEMENT $\geq 15\%$ (1 PT), 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	202 (33.0) 14 (2.3)	602	265 (44.0) 21 (3.5)	1.78 [1.38, 2.30]	1.44 [1.21, 1.67]	13.41 [7.58, 19.25]	<0.0001
Attack 2	194	56 (28.9) 11 (5.7)	971	414 (42.6) 41 (4.2)	2.89 [1.98, 4.23]	2.08 [1.48, 2.69]	22.28 [15.56, 29.00]	<0.0001
Attack 3	188	58 (30.9) 10 (5.3)	912	396 (43.4) 27 (3.0)	2.11 [1.45, 3.07]	1.65 [1.20, 2.09]	16.48 [9.05, 23.91]	<0.0001
Attack 4	171	53 (31.0) 11 (6.4)	860	425 (49.4) 39 (4.5)	2.70 [1.82, 4.02]	1.90 [1.35, 2.44]	22.38 [14.57, 30.18]	<0.0001
Overall effect	1166	369 (31.6) 46 (3.9)	3345	1500 (44.8) 128 (3.8)	2.33 [1.97, 2.76]	1.74 [1.53, 1.96]	18.79 [15.39, 22.19]	<0.0001
Interaction								0.1396

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=point, RD=Risk difference, RR=Relative risk

Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.12.2.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF CFS IMPROVEMENT $\geq 15\%$ (1 PT), 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	253 (41.3) 42 (6.9)	602	366 (60.8) 41 (6.8)	3.05 [2.30, 4.06]	1.67 [1.44, 1.90]	27.03 [20.49, 33.58]	<0.0001
Attack 2	194	85 (43.8) 19 (9.8)	971	578 (59.5) 61 (6.3)	3.47 [2.21, 5.46]	1.82 [1.34, 2.30]	30.09 [19.67, 40.52]	<0.0001
Attack 3	188	81 (43.1) 9 (4.8)	912	553 (60.6) 74 (8.1)	2.95 [1.92, 4.53]	1.65 [1.26, 2.05]	26.26 [16.08, 36.44]	<0.0001
Attack 4	171	70 (40.9) 12 (7.0)	860	524 (60.9) 68 (7.9)	3.36 [2.15, 5.27]	1.85 [1.34, 2.35]	29.43 [19.24, 39.62]	<0.0001
Overall effect	1166	489 (41.9) 82 (7.0)	3345	2021 (60.4) 244 (7.3)	3.20 [2.63, 3.90]	1.74 [1.55, 1.94]	28.24 [23.68, 32.81]	<0.0001
Interaction								0.9437

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=point, RD=Risk difference, RR=Relative risk

Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.12.2.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF CFS IMPROVEMENT $\geq 15\%$ (1 PT), 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	326 (53.2) 85 (13.9)	602	376 (62.5) 82 (13.6)	1.73 [1.26, 2.38]	1.22 [1.08, 1.35]	12.49 [5.29, 19.70]	0.0008
Attack 2	194	105 (54.1) 38 (19.6)	971	597 (61.5) 150 (15.4)	2.08 [1.28, 3.36]	1.32 [1.04, 1.59]	16.97 [5.36, 28.58]	0.0030
Attack 3	188	103 (54.8) 21 (11.2)	912	587 (64.4) 125 (13.7)	1.82 [1.10, 3.01]	1.22 [0.99, 1.45]	13.21 [1.55, 24.86]	0.0195
Attack 4	171	99 (57.9) 25 (14.6)	860	545 (63.4) 135 (15.7)	1.47 [0.90, 2.41]	1.15 [0.93, 1.37]	8.85 [-2.77, 20.48]	0.1237
Overall effect	1166	633 (54.3) 169 (14.5)	3345	2105 (62.9) 492 (14.7)	1.76 [1.42, 2.19]	1.22 [1.12, 1.33]	12.89 [7.79, 17.98]	<0.0001
Interaction								0.8103

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=point, RD=Risk difference, RR=Relative risk
 Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.13.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF EQ 5D VAS IMPROVEMENT $\geq 15\%$ (15 PT), 24 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%)	N	n (%)	OR	RR	RD	p-value
Attack		k (%)		k (%)	[95% CI]	[95% CI]	[95% CI]	
Attack 1	613	342 (55.8)	602	413 (68.6)	2.10	1.02	1.83	<0.0001
		48 (7.8)		44 (7.3)	[1.62, 2.72]	[1.01, 1.03]	[0.82, 2.83]	
Attack 2	194	128 (66.0)	971	674 (69.4)	1.21	1.00	0.25	0.3329
		20 (10.3)		78 (8.0)	[0.82, 1.77]	[1.00, 1.01]	[-0.31, 0.82]	
Attack 3	188	102 (54.3)	912	660 (72.4)	2.29	1.02	1.50	<0.0001
		20 (10.6)		59 (6.5)	[1.59, 3.32]	[1.00, 1.03]	[0.37, 2.63]	
Attack 4	171	109 (63.7)	860	627 (72.9)	2.06	1.01	1.34	0.0004
		18 (10.5)		60 (7.0)	[1.38, 3.08]	[1.00, 1.03]	[0.22, 2.46]	
Overall effect	1166	681 (58.4)	3345	2374 (71.0)	1.86	1.01	1.13	<0.0001
		106 (9.1)		241 (7.2)	[1.57, 2.20]	[1.01, 1.02]	[0.63, 1.64]	
Interaction								0.0771

The MITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, k=Number of imputed values, MITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=points, RD=Risk difference, RR=Relative risk

Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline EQ 5D VAS score and baseline EQ 5D VAS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.14.1.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS NORMAL FUNCTION (FDS = 0), 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	246 (40.1) 14 (2.3)	602	289 (48.0) 21 (3.5)	1.68 [1.30, 2.19]	1.36 [1.15, 1.57]	12.54 [6.32, 18.76]	<0.0001
Attack 2	194	53 (27.3) 11 (5.7)	971	491 (50.6) 41 (4.2)	3.20 [2.20, 4.64]	2.10 [1.52, 2.67]	26.18 [19.02, 33.34]	<0.0001
Attack 3	188	68 (36.2) 10 (5.3)	912	429 (47.0) 27 (3.0)	1.83 [1.29, 2.60]	1.45 [1.11, 1.79]	14.25 [6.48, 22.02]	0.0007
Attack 4	171	64 (37.4) 11 (6.4)	860	438 (50.9) 39 (4.5)	2.01 [1.41, 2.86]	1.49 [1.16, 1.82]	16.90 [8.75, 25.05]	0.0001
Overall effect	1166	431 (37.0) 46 (3.9)	3345	1647 (49.2) 128 (3.8)	2.11 [1.80, 2.47]	1.57 [1.40, 1.73]	17.67 [14.12, 21.21]	<0.0001
Interaction								0.0525

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 27032026

TABLE 4.2.14.1.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF FDS NORMAL FUNCTION (FDS = 0), 4 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	284 (46.3) 41 (6.7)	602	392 (65.1) 40 (6.6)	2.77 [2.15, 3.58]	1.56 [1.38, 1.74]	24.55 [18.66, 30.44]	<0.0001
Attack 2	194	73 (37.6) 19 (9.8)	971	671 (69.1) 61 (6.3)	4.04 [2.86, 5.69]	1.87 [1.50, 2.23]	33.17 [25.25, 41.10]	<0.0001
Attack 3	188	84 (44.7) 9 (4.8)	912	595 (65.2) 74 (8.1)	2.66 [1.92, 3.69]	1.55 [1.28, 1.81]	23.68 [15.79, 31.56]	<0.0001
Attack 4	171	79 (46.2) 12 (7.0)	860	578 (67.2) 68 (7.9)	2.45 [1.74, 3.45]	1.44 [1.20, 1.68]	21.29 [12.99, 29.58]	<0.0001
Overall effect	1166	520 (44.6) 81 (6.9)	3345	2236 (66.8) 243 (7.3)	2.92 [2.51, 3.40]	1.59 [1.47, 1.72]	25.73 [22.11, 29.35]	<0.0001
Interaction								0.1911

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

AbbVie Inc. CONFIDENTIAL Clinical Data Cutoff Date: 07072025 / Final, Snapshot: I; Date of Table Generation 27032026

TABLE 4.2.14.1.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATA CUT: 07072025)
 ANALYSIS OF FDS NORMAL FUNCTION (FDS = 0), 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	384 (62.6) 85 (13.9)	602	444 (73.8) 81 (13.5)	1.88 [1.47, 2.40]	1.21 [1.12, 1.31]	13.33 [8.24, 18.42]	<0.0001
Attack 2	194	111 (57.2) 38 (19.6)	971	721 (74.3) 150 (15.4)	2.04 [1.50, 2.77]	1.26 [1.12, 1.41]	15.58 [8.51, 22.65]	<0.0001
Attack 3	188	114 (60.6) 21 (11.2)	912	700 (76.8) 125 (13.7)	2.08 [1.51, 2.85]	1.24 [1.10, 1.38]	15.05 [7.97, 22.13]	<0.0001
Attack 4	171	104 (60.8) 25 (14.6)	860	638 (74.2) 135 (15.7)	1.84 [1.32, 2.55]	1.21 [1.07, 1.35]	13.00 [5.56, 20.45]	0.0003
Overall effect	1166	713 (61.1) 169 (14.5)	3345	2503 (74.8) 491 (14.7)	1.96 [1.70, 2.25]	1.23 [1.17, 1.29]	14.25 [11.09, 17.42]	<0.0001
Interaction								0.9351

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, RD=Risk difference, RR=Relative risk
 Percentages are calculated as 100 x (n/N) or 100 x (k/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.14.2.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS IMPROVEMENT $\geq 15\%$ (1 PT), 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	208 (33.9) 15 (2.4)	602	246 (40.9) 22 (3.7)	1.59 [1.23, 2.06]	1.35 [1.12, 1.58]	10.52 [4.70, 16.33]	0.0004
Attack 2	194	52 (26.8) 12 (6.2)	971	432 (44.5) 41 (4.2)	3.70 [2.48, 5.52]	2.50 [1.71, 3.29]	26.64 [20.14, 33.15]	<0.0001
Attack 3	188	52 (27.7) 10 (5.3)	912	393 (43.1) 28 (3.1)	2.15 [1.47, 3.16]	1.69 [1.21, 2.16]	16.47 [9.14, 23.80]	<0.0001
Attack 4	171	47 (27.5) 11 (6.4)	860	409 (47.6) 40 (4.7)	2.93 [1.98, 4.33]	2.05 [1.45, 2.66]	23.34 [16.13, 30.55]	<0.0001
Overall effect	1166	359 (30.8) 48 (4.1)	3345	1480 (44.2) 131 (3.9)	2.47 [2.08, 2.93]	1.84 [1.61, 2.08]	19.50 [16.22, 22.79]	<0.0001
Interaction								0.0033

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=point, RD=Risk difference, RR=Relative risk
 Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.14.2.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS IMPROVEMENT $\geq 15\%$ (1 PT), 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

Attack	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			p-value
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	613	242 (39.5) 42 (6.9)	602	347 (57.6) 41 (6.8)	3.35 [2.40, 4.67]	1.82 [1.51, 2.13]	29.31 [21.69, 36.92]	<0.0001
Attack 2	194	78 (40.2) 20 (10.3)	971	569 (58.6) 61 (6.3)	4.35 [2.71, 7.00]	2.16 [1.50, 2.82]	35.13 [24.96, 45.30]	<0.0001
Attack 3	188	68 (36.2) 9 (4.8)	912	525 (57.6) 75 (8.2)	3.04 [2.00, 4.64]	1.78 [1.32, 2.25]	27.09 [17.48, 36.71]	<0.0001
Attack 4	171	64 (37.4) 12 (7.0)	860	508 (59.1) 69 (8.0)	3.62 [2.23, 5.88]	1.98 [1.36, 2.59]	30.99 [20.36, 41.62]	<0.0001
Overall effect	1166	452 (38.8) 83 (7.1)	3345	1949 (58.3) 246 (7.4)	3.56 [2.90, 4.37]	1.93 [1.68, 2.17]	30.68 [26.09, 35.27]	<0.0001
Interaction								0.7324

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=point, RD=Risk difference, RR=Relative risk
 Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.14.2.3

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS IMPROVEMENT $\geq 15\%$ (1 PT), 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----		---- Atogepant ----		----- Atogepant vs. Placebo -----			
	N	n (%) k (%)	N	n (%) k (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	p-value
Attack								
Attack 1	613	313 (51.1) 85 (13.9)	602	358 (59.5) 82 (13.6)	1.78 [1.27, 2.51]	1.25 [1.08, 1.42]	13.70 [5.71, 21.70]	0.0010
Attack 2	194	98 (50.5) 39 (20.1)	971	597 (61.5) 150 (15.4)	2.77 [1.78, 4.32]	1.54 [1.19, 1.88]	24.32 [13.63, 35.02]	<0.0001
Attack 3	188	94 (50.0) 21 (11.2)	912	569 (62.4) 125 (13.7)	1.81 [1.18, 2.79]	1.25 [1.02, 1.48]	13.88 [3.53, 24.24]	0.0066
Attack 4	171	94 (55.0) 25 (14.6)	860	516 (60.0) 135 (15.7)	1.28 [0.84, 1.96]	1.10 [0.91, 1.29]	5.83 [-4.40, 16.05]	0.2567
Overall effect	1166	599 (51.4) 170 (14.6)	3345	2040 (61.0) 492 (14.7)	1.84 [1.52, 2.23]	1.27 [1.16, 1.38]	14.45 [9.78, 19.13]	<0.0001
Interaction								0.1163

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, k=Number of imputed values, mITT1=Modified intent to treat population of the DB phase, n=Number of events, N=Number of subjects with qualifying attack for a specific attack; for the overall assessment, subjects who received multiple study drugs will be counted multiple times, OR=Odds ratio, pt=point, RD=Risk difference, RR=Relative risk
 Percentages are calculated as $100 \times (n/N)$ or $100 \times (k/N)$.

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method. Missing values were imputed as non-responders. Observations were considered regardless of rescue medication.

For OR and RR, values > 1 indicate a favor of Atogepant. For RD, values > 0 indicate a favor of Atogepant.

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TABLE 4.2.15.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF CFS SCORE, 2 HOURS AFTER THE DB DOSE
 MITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	Baseline	LS Mean	N	Baseline	LS Mean	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	Change	n_obs (%)	Mean (SD)	Change	Difference	Mean Difference	p-value
			from BL			from BL	[95% CI]	[95% CI]	
Attack			(SE)			(SE)			
Attack 1	613	1.12	-0.37	602	1.17	-0.54	-0.17	-0.27	<0.0001
	599 (97.7)	(0.80)	(0.03)	581 (96.5)	(0.82)	(0.03)	[-0.24, -0.10]	[-0.39, -0.16]	
Attack 2	194	1.28	-0.21	971	1.14	-0.56	-0.36	-0.58	<0.0001
	183 (94.3)	(0.85)	(0.05)	930 (95.8)	(0.82)	(0.03)	[-0.45, -0.26]	[-0.74, -0.42]	
Attack 3	188	1.20	-0.28	912	1.18	-0.54	-0.26	-0.40	<0.0001
	178 (94.7)	(0.83)	(0.05)	885 (97.0)	(0.82)	(0.03)	[-0.36, -0.16]	[-0.57, -0.24]	
Attack 4	171	1.28	-0.30	860	1.25	-0.61	-0.31	-0.51	<0.0001
	160 (93.6)	(0.90)	(0.05)	821 (95.5)	(0.86)	(0.03)	[-0.42, -0.21]	[-0.68, -0.34]	
Overall effect	1166		-0.29	1187		-0.56	-0.27	-0.50	<0.0001
	1120 (96.1)		(0.03)	1184 (99.7)		(0.02)	[-0.32, -0.23]	[-0.58, -0.41]	
Interaction									0.0175

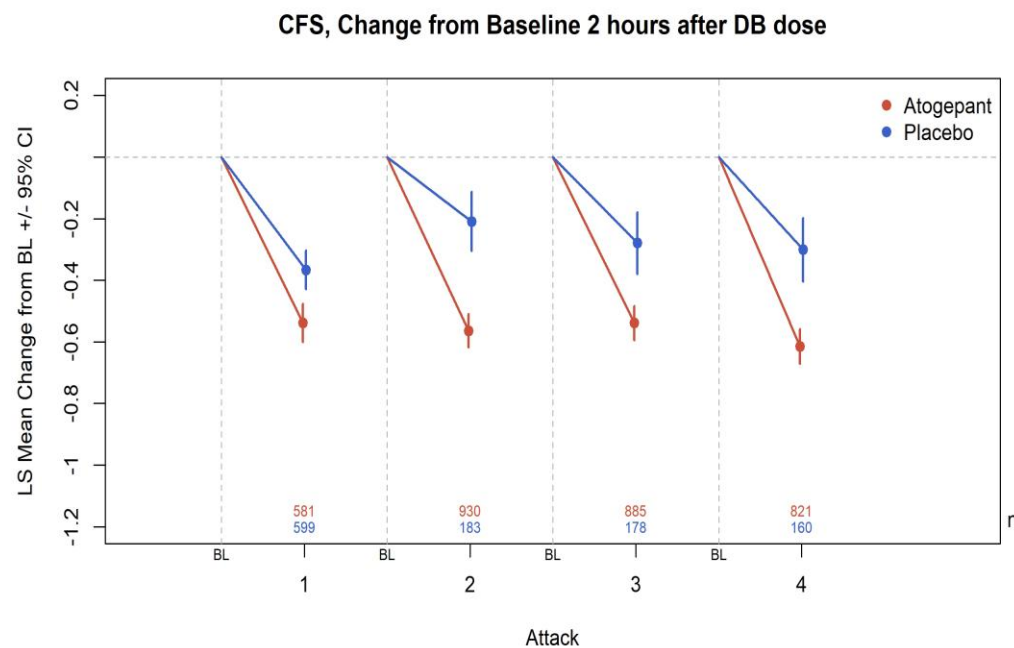
The MITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=Baseline, CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, LS=Least squares, MITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data. For LS mean change difference and standardized mean difference, values < 0 indicate a favor of Atogepant.

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FIGURE 4.2.1.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF CFS SCORE, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period. BL=baseline, CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point. The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.15.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF CFS SCORE, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

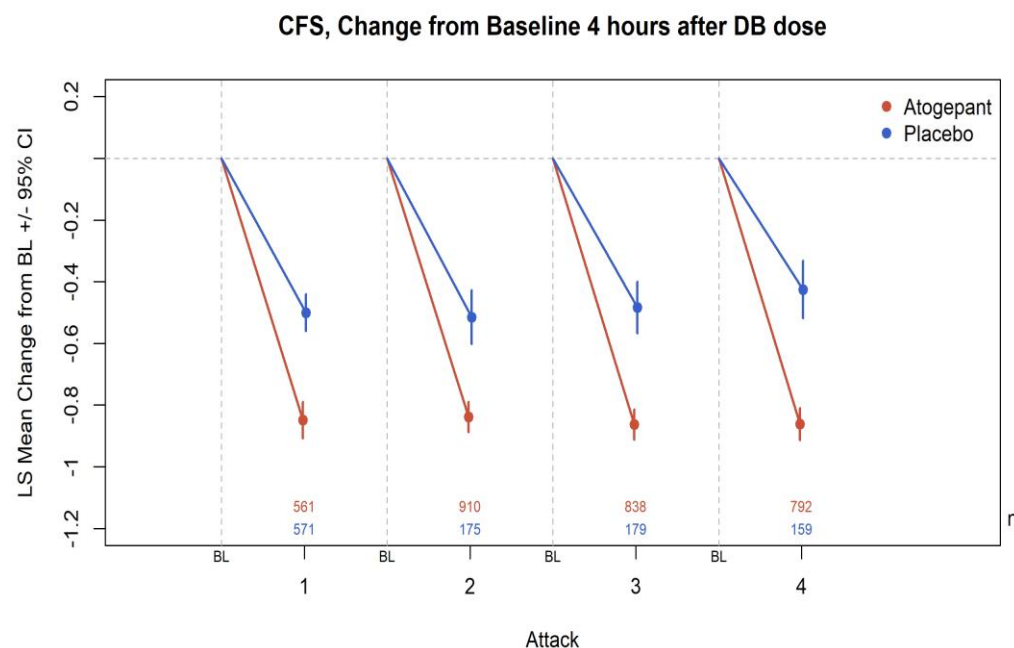
	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	baseline	LS Mean Change	N	baseline	LS Mean Change	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	from BL (SE)	n_obs (%)	Mean (SD)	from BL (SE)	Difference [95% CI]	Mean Difference [95% CI]	p-value
Attack	613	1.13	-0.50	602	1.18	-0.85	-0.35	-0.58	<0.0001
Attack 1	571 (93.1)	(0.82)	(0.03)	561 (93.2)	(0.83)	(0.03)	[-0.42, -0.28]	[-0.70, -0.46]	
Attack 2	194	1.30	-0.51	971	1.15	-0.84	-0.32	-0.59	<0.0001
	175 (90.2)	(0.86)	(0.04)	910 (93.7)	(0.81)	(0.03)	[-0.41, -0.24]	[-0.75, -0.43]	
Attack 3	188	1.19	-0.48	912	1.19	-0.86	-0.38	-0.72	<0.0001
	179 (95.2)	(0.83)	(0.04)	838 (91.9)	(0.82)	(0.02)	[-0.46, -0.29]	[-0.89, -0.56]	
Attack 4	171	1.29	-0.42	860	1.24	-0.86	-0.44	-0.78	<0.0001
	159 (93.0)	(0.90)	(0.05)	792 (92.1)	(0.86)	(0.03)	[-0.53, -0.34]	[-0.95, -0.60]	
Overall effect	1166		-0.48	1187		-0.85	-0.37	-0.76	<0.0001
	1084 (93.0)		(0.03)	1169 (98.5)		(0.02)	[-0.41, -0.33]	[-0.85, -0.68]	
Interaction									0.3608

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data. For LS mean change difference and standardized mean difference, values < 0 indicate a favor of Atogepant.

FIGURE 4.2.1.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF CFS SCORE, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and Baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.15.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF CFS SCORE, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

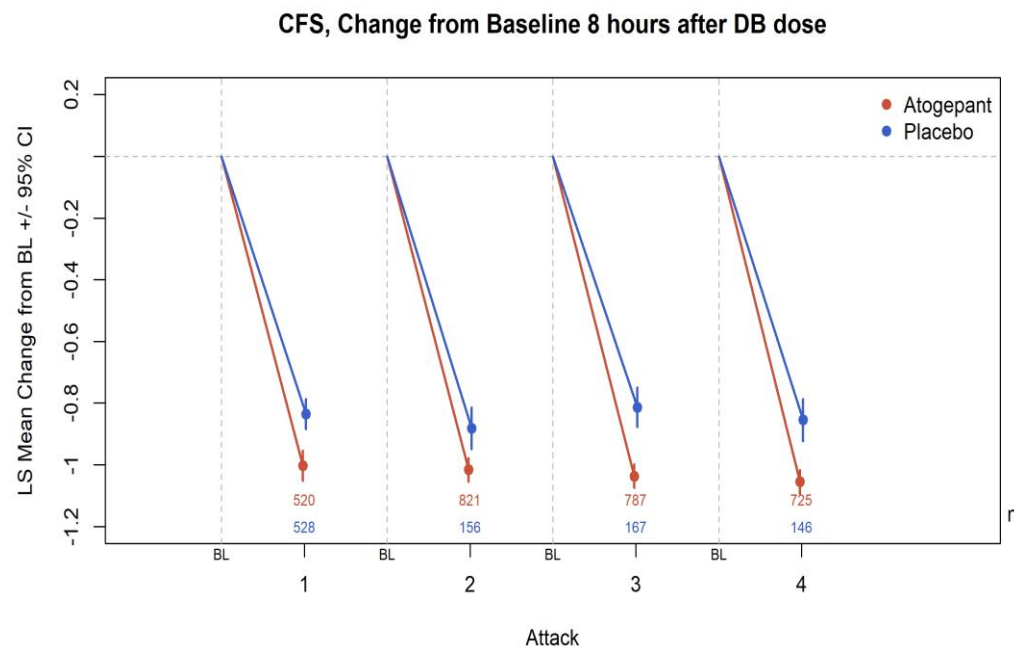
	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	baseline	LS Mean Change	N	baseline	LS Mean Change	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	from BL (SE)	n_obs (%)	Mean (SD)	from BL (SE)	Difference [95% CI]	Mean Difference [95% CI]	p-value
Attack	613	1.12	-0.84	602	1.19	-1.00	-0.17	-0.35	<0.0001
Attack 1	528 (86.1)	(0.81)	(0.02)	520 (86.4)	(0.83)	(0.02)	[-0.23, -0.11]	[-0.47, -0.23]	
Attack 2	194	1.28	-0.88	971	1.17	-1.02	-0.13	-0.33	0.0001
	156 (80.4)	(0.86)	(0.03)	821 (84.6)	(0.81)	(0.02)	[-0.20, -0.07]	[-0.51, -0.16]	
Attack 3	188	1.22	-0.81	912	1.18	-1.04	-0.22	-0.57	<0.0001
	167 (88.8)	(0.84)	(0.03)	787 (86.3)	(0.82)	(0.02)	[-0.29, -0.16]	[-0.74, -0.40]	
Attack 4	171	1.31	-0.85	860	1.25	-1.06	-0.20	-0.51	<0.0001
	146 (85.4)	(0.89)	(0.04)	725 (84.3)	(0.86)	(0.02)	[-0.27, -0.13]	[-0.69, -0.33]	
Overall effect	1166		-0.85	1187		-1.03	-0.18	-0.50	<0.0001
	997 (85.5)		(0.02)	1134 (95.5)		(0.02)	[-0.21, -0.15]	[-0.59, -0.42]	
Interaction									0.2773

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline CFS score and Baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data. For LS mean change difference and standardized mean difference, values < 0 indicate a favor of Atogepant.

FIGURE 4.2.1.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF CFS SCORE, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period. BL=baseline, CFS=Cognitive Function Scale, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point. The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), Baseline CFS score and baseline CFS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.16.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF EQ 5D VAS, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	baseline	LS Mean Change	N	baseline	LS Mean Change	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	from BL (SE)	n_obs (%)	Mean (SD)	from BL (SE)	Difference [95% CI]	Mean Difference [95% CI]	p-value
Attack	613	56.45	19.72	602	57.25	26.95	7.23	0.48	<0.0001
Attack 1	565 (92.2)	(19.34)	(0.82)	558 (92.7)	(19.23)	(0.82)	[5.46, 9.00]	[0.36, 0.60]	
Attack 2	194	55.09	23.21	971	55.43	27.65	4.44	0.36	<0.0001
	174 (89.7)	(19.46)	(1.07)	893 (92.0)	(19.66)	(0.67)	[2.43, 6.46]	[0.20, 0.52]	
Attack 3	188	54.50	18.86	912	53.82	28.36	9.50	0.76	<0.0001
	168 (89.4)	(19.22)	(1.09)	853 (93.5)	(20.30)	(0.68)	[7.44, 11.56]	[0.59, 0.93]	
Attack 4	171	51.66	21.76	860	53.07	28.52	6.76	0.59	<0.0001
	153 (89.5)	(19.74)	(1.07)	800 (93.0)	(21.07)	(0.66)	[4.76, 8.75]	[0.41, 0.76]	
Overall effect	1166		20.89	1187		27.87	6.98	0.65	<0.0001
	1060 (90.9)		(0.68)	1148 (96.7)		(0.59)	[6.09, 7.88]	[0.56, 0.74]	
Interaction									0.0096

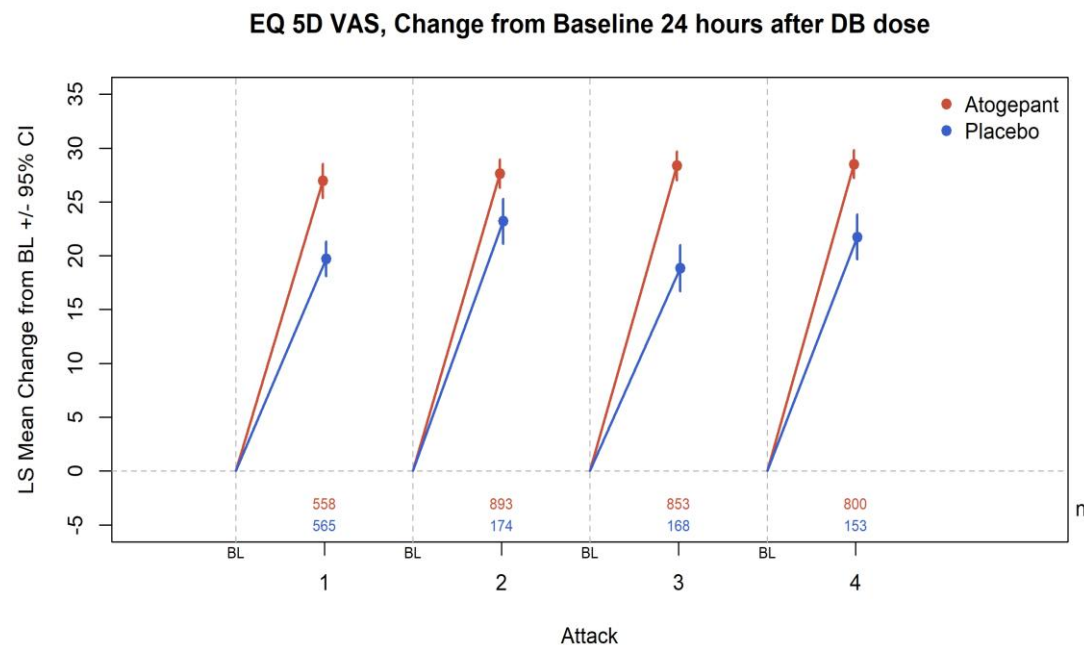
The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, SD=Standard Deviation, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline EQ 5D VAS score and baseline EQ 5D VAS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data.

For LS mean change difference and standardized mean difference, values > 0 indicate a favor of Atogepant.

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 FIGURE 4.2.2.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF EQ 5D VAS, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, EQ 5D VAS=European Quality of Life Visual Analog Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline EQ 5D VAS score and baseline EQ 5D VAS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.17.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS SCORE, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	baseline	LS Mean	N	baseline	LS Mean	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	Change	n_obs (%)	Mean (SD)	Change	Difference	Mean Difference	p-value
			from BL			from BL	[95% CI]	[95% CI]	
Attack			(SE)			(SE)			
Attack 1	613	1.11	-0.35	602	1.13	-0.54	-0.19	-0.30	<0.0001
	598 (97.6)	(0.86)	(0.03)	580 (96.3)	(0.89)	(0.03)	[-0.26, -0.12]	[-0.41, -0.18]	
Attack 2	194	1.29	-0.22	971	1.13	-0.58	-0.36	-0.58	<0.0001
	182 (93.8)	(0.91)	(0.05)	930 (95.8)	(0.84)	(0.03)	[-0.46, -0.26]	[-0.74, -0.42]	
Attack 3	188	1.11	-0.31	912	1.16	-0.53	-0.22	-0.35	<0.0001
	178 (94.7)	(0.88)	(0.05)	884 (96.9)	(0.85)	(0.03)	[-0.32, -0.12]	[-0.52, -0.19]	
Attack 4	171	1.17	-0.31	860	1.20	-0.61	-0.30	-0.50	<0.0001
	160 (93.6)	(0.91)	(0.05)	820 (95.3)	(0.87)	(0.03)	[-0.40, -0.20]	[-0.68, -0.33]	
Overall effect	1166		-0.30	1187		-0.57	-0.27	-0.50	<0.0001
	1118 (95.9)		(0.03)	1184 (99.7)		(0.02)	[-0.31, -0.22]	[-0.58, -0.41]	
Interaction									0.0433

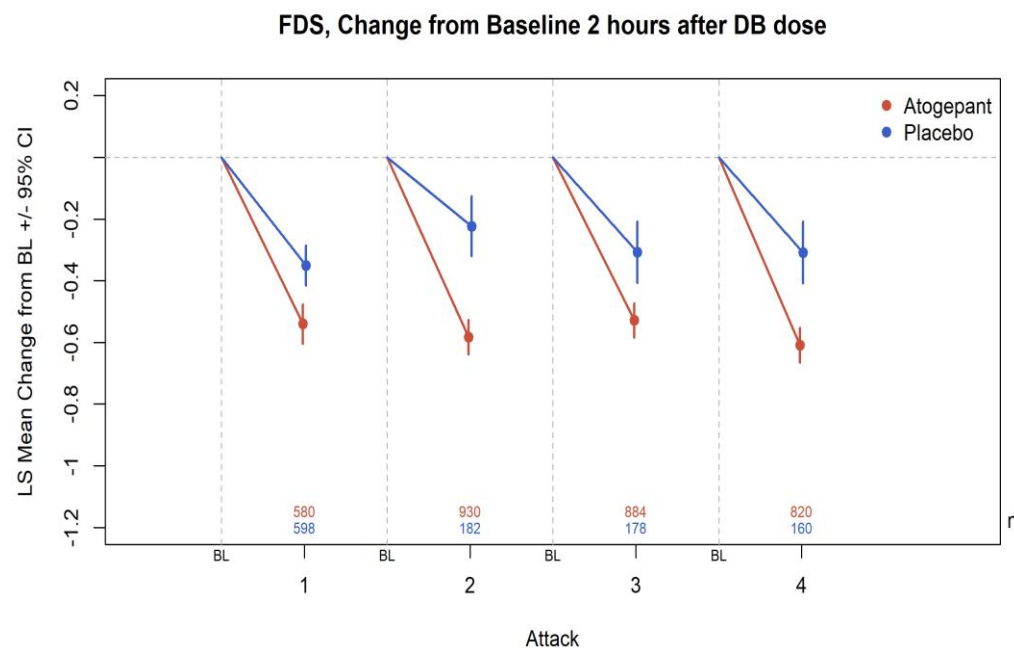
The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data. For LS mean change difference and standardized mean difference, values < 0 indicate a favor of Atogepant.

FIGURE 4.2.3.1

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF FDS SCORE, 2 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.17.2
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS SCORE, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	baseline	LS Mean	N	baseline	LS Mean	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	Change	n_obs (%)	Mean (SD)	Change	Difference	Mean Difference	p-value
			from BL			from BL	[95% CI]	[95% CI]	
Attack			(SE)			(SE)			
Attack 1	613	1.13	-0.46	602	1.14	-0.82	-0.36	-0.56	<0.0001
	571 (93.1)	(0.87)	(0.03)	561 (93.2)	(0.89)	(0.03)	[-0.44, -0.29]	[-0.68, -0.44]	
Attack 2	194	1.29	-0.44	971	1.13	-0.84	-0.40	-0.71	<0.0001
	174 (89.7)	(0.91)	(0.05)	910 (93.7)	(0.84)	(0.03)	[-0.49, -0.31]	[-0.88, -0.55]	
Attack 3	188	1.09	-0.40	912	1.17	-0.84	-0.44	-0.80	<0.0001
	179 (95.2)	(0.87)	(0.04)	837 (91.8)	(0.85)	(0.03)	[-0.52, -0.35]	[-0.96, -0.63]	
Attack 4	171	1.18	-0.47	860	1.20	-0.86	-0.40	-0.73	<0.0001
	159 (93.0)	(0.91)	(0.05)	791 (92.0)	(0.86)	(0.03)	[-0.49, -0.30]	[-0.90, -0.55]	
Overall effect	1166		-0.44	1187		-0.84	-0.40	-0.80	<0.0001
	1083 (92.9)		(0.03)	1169 (98.5)		(0.02)	[-0.44, -0.36]	[-0.89, -0.72]	
Interaction									0.6681

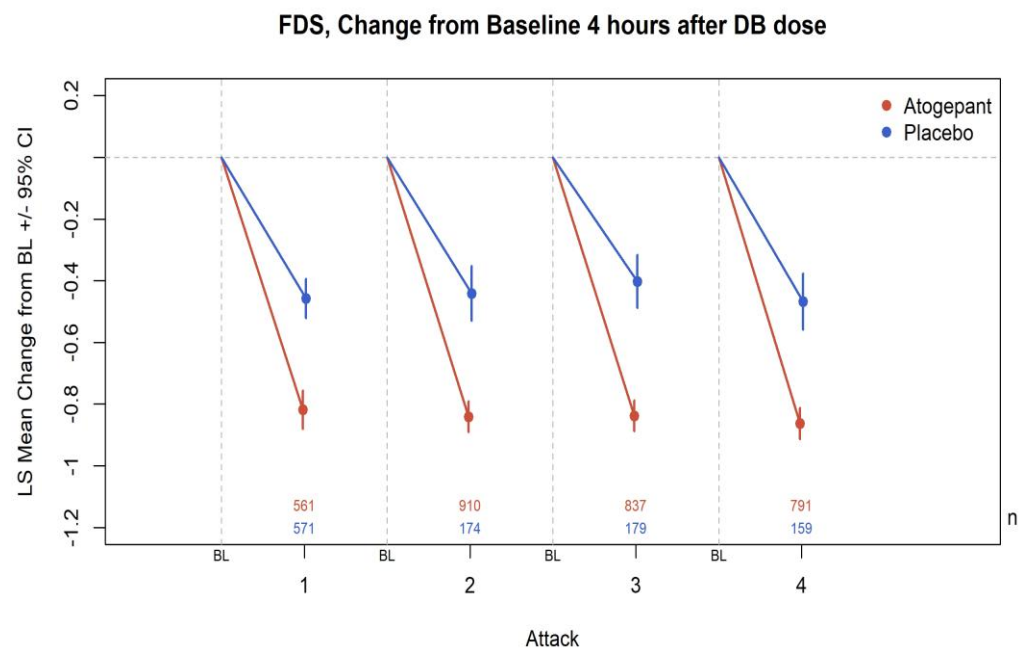
The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data. For LS mean change difference and standardized mean difference, values < 0 indicate a favor of Atogepant.

FIGURE 4.2.3.2

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF FDS SCORE, 4 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.17.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF FDS SCORE, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

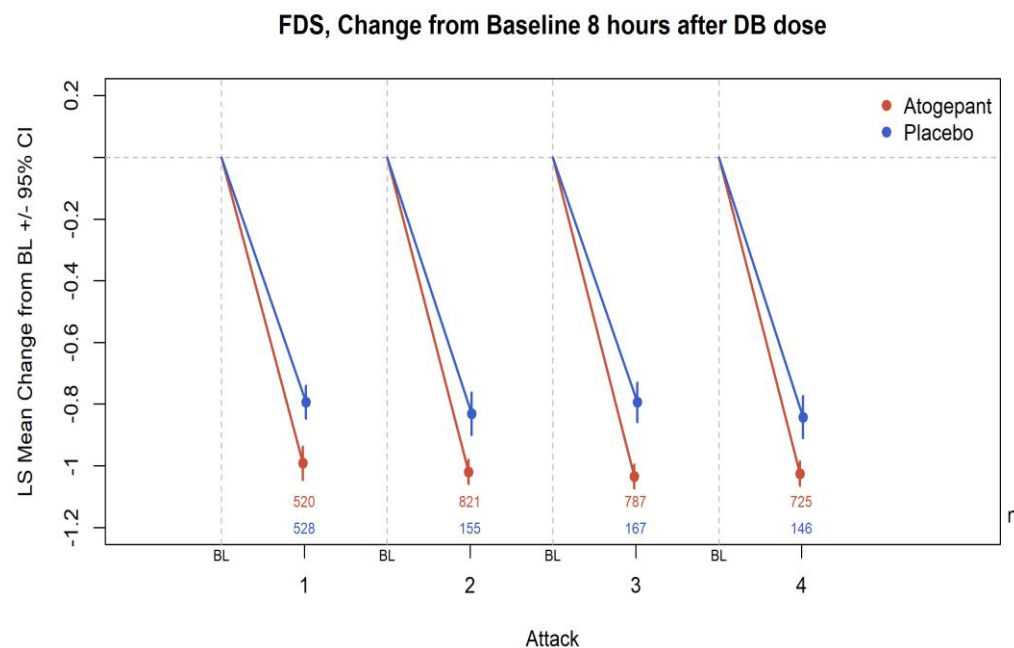
	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	baseline	LS Mean	N	baseline	LS Mean	LS Mean Change	Standardized	
	n_obs (%)	Mean (SD)	Change	n_obs (%)	Mean (SD)	Change	Difference	Mean Difference	p-value
			from BL			from BL	[95% CI]	[95% CI]	
Attack			(SE)			(SE)			
Attack 1	613	1.13	-0.79	602	1.16	-0.99	-0.20	-0.37	<0.0001
	528 (86.1)	(0.87)	(0.03)	520 (86.4)	(0.89)	(0.03)	[-0.26, -0.13]	[-0.49, -0.24]	
Attack 2	194	1.27	-0.83	971	1.16	-1.02	-0.19	-0.47	<0.0001
	155 (79.9)	(0.89)	(0.04)	821 (84.6)	(0.83)	(0.02)	[-0.26, -0.12]	[-0.64, -0.29]	
Attack 3	188	1.11	-0.79	912	1.16	-1.03	-0.24	-0.63	<0.0001
	167 (88.8)	(0.87)	(0.03)	787 (86.3)	(0.85)	(0.02)	[-0.30, -0.18]	[-0.80, -0.46]	
Attack 4	171	1.19	-0.84	860	1.19	-1.03	-0.18	-0.47	<0.0001
	146 (85.4)	(0.89)	(0.04)	725 (84.3)	(0.85)	(0.02)	[-0.25, -0.11]	[-0.65, -0.30]	
Overall effect	1166		-0.82	1187		-1.02	-0.20	-0.55	<0.0001
	996 (85.4)		(0.02)	1134 (95.5)		(0.02)	[-0.23, -0.17]	[-0.64, -0.46]	
Interaction									0.6244

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n_obs=Number of subjects with observed measurements at both baseline and the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data. For LS mean change difference and standardized mean difference, values < 0 indicate a favor of Atogepant.

FIGURE 4.2.3.3
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 TIME COURSE PLOT OF FDS SCORE, 8 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, FDS=Functional Disability Scale, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, n=Number of subjects with observed measurements at both baseline and the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), baseline headache severity (moderate or severe), baseline FDS score and baseline FDS score-by-attack interaction. The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.18.1.1

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF MQOLQ WORK FUNCTIONING, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	Post- baseline	LS Mean	N	Post- baseline	LS Mean	LS Mean Difference	Standardized Mean Difference	p-value
	n_obs (%)	Mean (SD)	(SE)	n_obs (%)	Mean (SD)	(SE)	[95% CI]	[95% CI]	
Attack	613	13.00	13.05	602	14.33	14.55	1.50	0.40	<0.0001
Attack 1	565 (92.2)	(4.45)	(0.22)	558 (92.7)	(4.37)	(0.22)	[1.07, 1.94]	[0.29, 0.52]	
Attack 2	194	13.03	13.38	971	14.42	14.52	1.14	0.34	<0.0001
	174 (89.7)	(4.13)	(0.30)	894 (92.1)	(4.31)	(0.19)	[0.60, 1.69]	[0.18, 0.50]	
Attack 3	188	12.57	12.82	912	14.39	14.53	1.71	0.53	<0.0001
	167 (88.8)	(4.59)	(0.30)	855 (93.8)	(4.22)	(0.19)	[1.17, 2.26]	[0.36, 0.69]	
Attack 4	171	12.93	13.14	860	14.46	14.57	1.43	0.44	<0.0001
	153 (89.5)	(4.61)	(0.31)	801 (93.1)	(4.30)	(0.20)	[0.86, 2.00]	[0.26, 0.61]	
Overall effect	1166		13.10	1187		14.54	1.45	0.51	<0.0001
	1059 (90.8)		(0.19)	1150 (96.9)		(0.17)	[1.21, 1.69]	[0.42, 0.59]	
Interaction									0.5503

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n_obs=Number of subjects with observed measurements at the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error

Percentages are calculated as $100 \times (n_obs/N)$.

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data.

For LS mean change difference and standardized mean difference, values > 0 indicate a favor of Atogepant.

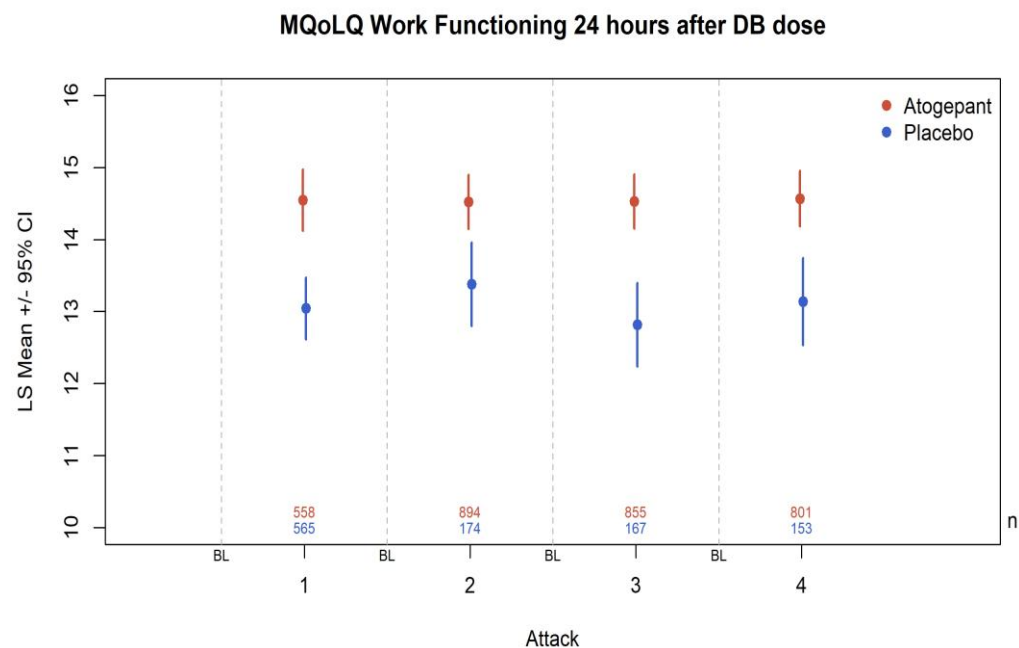
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FIGURE 4.2.4.1

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

TIME COURSE PLOT OF MQoLQ WORK FUNCTIONING, 24 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observed measurements at the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.18.2.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF MQOLQ SOCIAL FUNCTIONING, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	Post- baseline	LS Mean	N	Post- baseline	LS Mean	LS Mean Difference	Standardized Mean Difference	p-value
	n_obs (%)	Mean (SD)	(SE)	n_obs (%)	Mean (SD)	(SE)	[95% CI]	[95% CI]	
Attack									
Attack 1	613	13.03	13.30	602	14.49	14.96	1.67	0.44	<0.0001
	565 (92.2)	(4.80)	(0.23)	558 (92.7)	(4.44)	(0.23)	[1.22, 2.11]	[0.32, 0.56]	
Attack 2	194	13.05	13.58	971	14.56	14.91	1.33	0.37	<0.0001
	174 (89.7)	(4.60)	(0.31)	894 (92.1)	(4.56)	(0.20)	[0.75, 1.90]	[0.21, 0.54]	
Attack 3	188	12.78	13.42	912	14.65	14.96	1.54	0.46	<0.0001
	167 (88.8)	(4.80)	(0.30)	855 (93.8)	(4.33)	(0.20)	[0.99, 2.10]	[0.30, 0.63]	
Attack 4	171	12.55	13.07	860	14.65	14.98	1.92	0.56	<0.0001
	153 (89.5)	(5.14)	(0.32)	801 (93.1)	(4.40)	(0.20)	[1.33, 2.51]	[0.39, 0.74]	
Overall effect	1166		13.34	1187		14.95	1.61	0.55	<0.0001
	1059 (90.8)		(0.20)	1150 (96.9)		(0.18)	[1.37, 1.86]	[0.46, 0.63]	
Interaction									0.5769

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n_obs=Number of subjects with observed measurements at the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error
 Percentages are calculated as 100 x (n_obs/N).

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data.

For LS mean change difference and standardized mean difference, values > 0 indicate a favor of Atogepant.

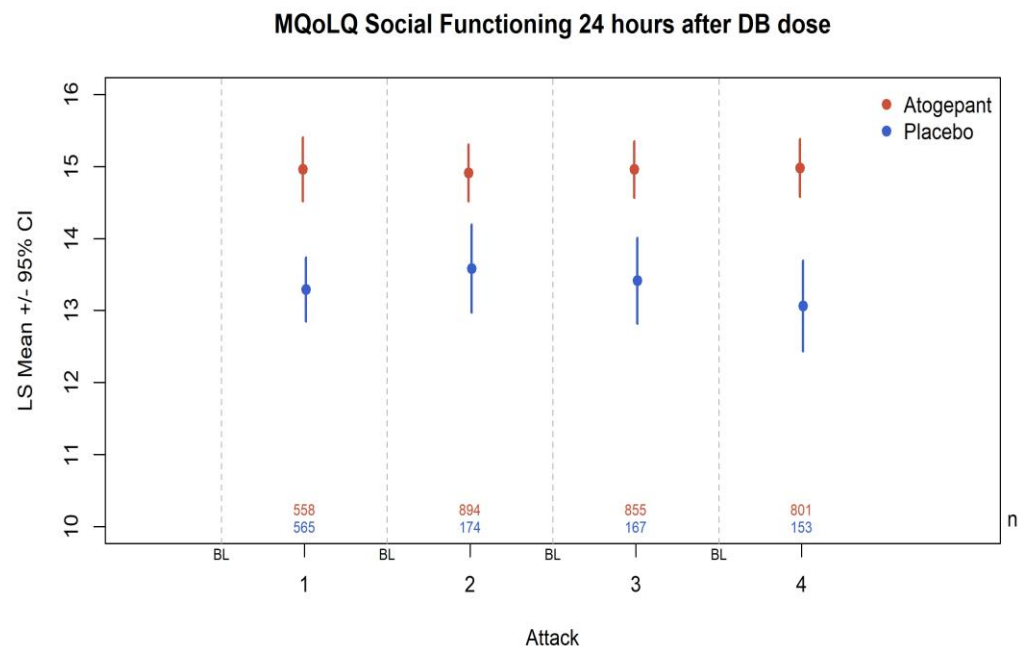
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FIGURE 4.2.4.2

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

TIME COURSE PLOT OF MQoLQ SOCIAL FUNCTIONING, 24 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observed measurements at the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.18.3.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF MQOLQ ENERGY VITALITY, 24 HOURS AFTER THE DB DOSE

MITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	Post- baseline	LS Mean	N	Post- baseline	LS Mean	LS Mean Difference	Standardized Mean Difference	p-value
	n_obs (%)	Mean (SD)	(SE)	n_obs (%)	Mean (SD)	(SE)	[95% CI]	[95% CI]	
Attack	613	12.44	12.79	602	14.46	14.92	2.13	0.55	<0.0001
Attack 1	565 (92.2)	(4.76)	(0.23)	558 (92.7)	(4.44)	(0.23)	[1.68, 2.58]	[0.43, 0.67]	
Attack 2	194	12.56	13.10	971	14.35	14.71	1.61	0.45	<0.0001
	174 (89.7)	(4.63)	(0.31)	894 (92.1)	(4.50)	(0.20)	[1.03, 2.19]	[0.29, 0.62]	
Attack 3	188	12.53	13.02	912	14.30	14.66	1.64	0.49	<0.0001
	167 (88.8)	(4.86)	(0.30)	855 (93.8)	(4.27)	(0.20)	[1.09, 2.20]	[0.32, 0.66]	
Attack 4	171	12.18	12.64	860	14.48	14.82	2.17	0.65	<0.0001
	153 (89.5)	(4.81)	(0.32)	801 (93.1)	(4.41)	(0.20)	[1.59, 2.76]	[0.47, 0.82]	
Overall effect	1166		12.89	1187		14.78	1.89	0.64	<0.0001
	1059 (90.8)		(0.20)	1150 (96.9)		(0.18)	[1.64, 2.14]	[0.55, 0.73]	
Interaction									0.3459

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n_obs=Number of subjects with observed measurements at the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error

Percentages are calculated as $100 \times (n_obs/N)$.

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data.

For LS mean change difference and standardized mean difference, values > 0 indicate a favor of Atogepant.

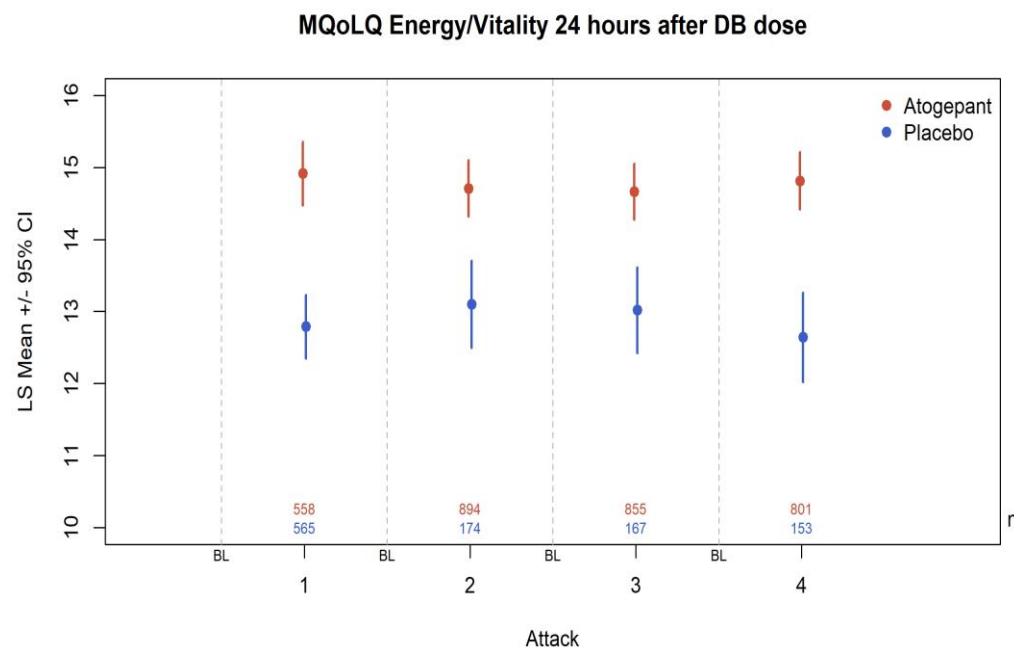
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FIGURE 4.2.4.3

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

TIME COURSE PLOT OF MQOLQ ENERGY VITALITY, 24 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observed measurements at the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.18.4.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF MQOLQ FEELINGS CONCERNS, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	Post- baseline	LS Mean	N	Post- baseline	LS Mean	LS Mean Difference	Standardized Mean Difference	p-value
	n_obs (%)	Mean (SD)	(SE)	n_obs (%)	Mean (SD)	(SE)	[95% CI]	[95% CI]	
Attack	613	11.67	11.97	602	13.90	14.28	2.31	0.66	<0.0001
Attack 1	565 (92.2)	(4.37)	(0.21)	558 (92.7)	(4.12)	(0.21)	[1.90, 2.72]	[0.54, 0.78]	
Attack 2	194	11.75	12.35	971	13.83	14.10	1.75	0.54	<0.0001
	174 (89.7)	(4.29)	(0.29)	894 (92.1)	(4.27)	(0.19)	[1.22, 2.27]	[0.38, 0.70]	
Attack 3	188	11.84	12.09	912	13.75	14.06	1.97	0.61	<0.0001
	167 (88.8)	(4.74)	(0.29)	855 (93.8)	(4.02)	(0.19)	[1.43, 2.50]	[0.44, 0.78]	
Attack 4	171	11.70	12.23	860	13.99	14.25	2.01	0.62	<0.0001
	153 (89.5)	(4.57)	(0.31)	801 (93.1)	(4.23)	(0.19)	[1.45, 2.57]	[0.44, 0.80]	
Overall effect	1166		12.16	1187		14.17	2.01	0.72	<0.0001
	1059 (90.8)		(0.19)	1150 (96.9)		(0.17)	[1.78, 2.24]	[0.64, 0.81]	
Interaction									0.4506

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n_obs=Number of subjects with observed measurements at the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error

Percentages are calculated as $100 \times (n_obs/N)$.

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data.

For LS mean change difference and standardized mean difference, values > 0 indicate a favor of Atogepant.

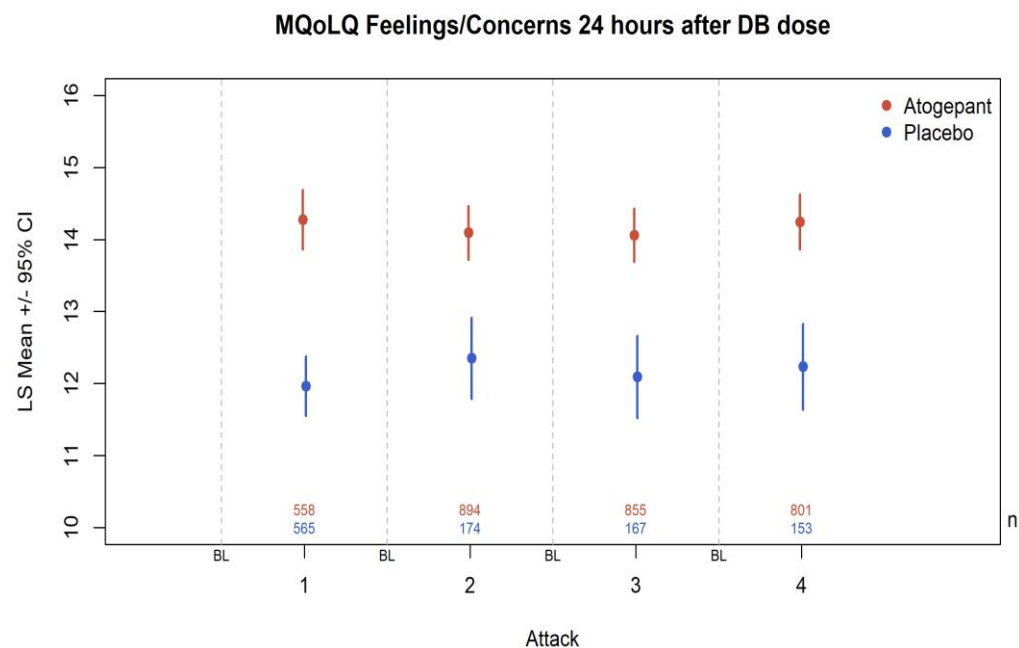
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FIGURE 4.2.4.4

ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

TIME COURSE PLOT OF MQoLQ FEELINGS CONCERNS, 24 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observed measurements at the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.2.18.5.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF MQOLQ MIGRAINE SYMPTOMS, 24 HOURS AFTER THE DB DOSE
 mITT1 ANALYSIS SET

	----- Placebo -----			----- Atogepant -----			----- Atogepant vs. Placebo -----		
	N	Post- baseline	LS Mean	N	Post- baseline	LS Mean	LS Mean Difference	Standardized Mean Difference	p-value
	n_obs (%)	Mean (SD)	(SE)	n_obs (%)	Mean (SD)	(SE)	[95% CI]	[95% CI]	
Attack	613	12.85	13.04	602	14.65	14.97	1.93	0.58	<0.0001
Attack 1	565 (92.2)	(4.12)	(0.20)	558 (92.7)	(3.88)	(0.20)	[1.53, 2.32]	[0.46, 0.70]	
Attack 2	194	12.90	13.35	971	14.60	14.77	1.42	0.45	<0.0001
	174 (89.7)	(3.97)	(0.27)	894 (92.1)	(3.95)	(0.18)	[0.91, 1.93]	[0.29, 0.62]	
Attack 3	188	12.65	13.04	912	14.38	14.61	1.56	0.50	<0.0001
	167 (88.8)	(4.42)	(0.28)	855 (93.8)	(3.88)	(0.18)	[1.04, 2.08]	[0.33, 0.67]	
Attack 4	171	12.96	13.30	860	14.60	14.80	1.50	0.47	<0.0001
	153 (89.5)	(4.25)	(0.29)	801 (93.1)	(3.92)	(0.18)	[0.95, 2.05]	[0.30, 0.65]	
Overall effect	1166		13.18	1187		14.79	1.60	0.59	<0.0001
	1059 (90.8)		(0.18)	1150 (96.9)		(0.16)	[1.38, 1.83]	[0.51, 0.68]	
Interaction									0.4297

The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n_obs=Number of subjects with observed measurements at the specified time point for a specific attack; for overall assessment, for at least one attack, N=Number of subjects with qualifying attack for a specific attack; for overall assessment, subjects who received multiple study drugs will be counted multiple times, SD=Standard Deviation, SE=Standard Error

Percentages are calculated as $100 \times (n_obs/N)$.

A mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger approximation, in case of non-convergence, alternative structures are used. The overall effect is computed across attacks. The interaction p-value refers to the treatment-by-attack interaction. The model only includes observed data.

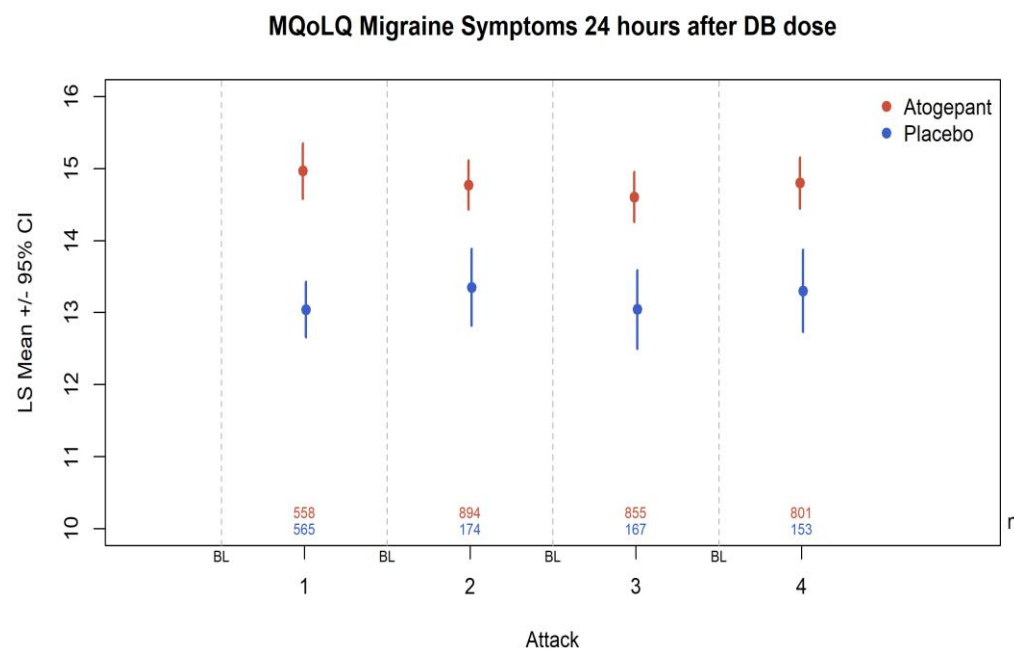
For LS mean change difference and standardized mean difference, values > 0 indicate a favor of Atogepant.

FIGURE 4.2.4.5

ATOGEPAANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

TIME COURSE PLOT OF MQoLQ MIGRAINE SYMPTOMS, 24 HOURS AFTER THE DB DOSE

mITT1 ANALYSIS SET



The mITT1 population of the DB phase includes all randomized subjects who received at least 1 dose of study drug during the DB treatment period, recorded a baseline migraine headache severity measurement, and had at least 1 postdose migraine headache severity or migraine-associated symptom measurement at or before the 48-hour timepoint based on headache eDiary for any attack during the DB period.

BL=baseline, CI=Confidence interval, DB=Double blind, LS=Least squares, mITT1=Modified intent to treat population of the DB phase, MQoLQ=Migraine Quality of Life Questionnaire, n=Number of subjects with observed measurements at the specified time point

The mixed model with repeated measures (MMRM) analysis includes treatment group, attack, treatment-by-attack interaction, region (Europe, China, Japan, and other), historical triptan-response stratum (triptan unsuitable, triptan experienced, or triptan naïve), use of medication for migraine prevention (yes/no), and baseline headache severity (moderate or severe). The model uses an unstructured covariance structure and Kenward-Roger-approximation, in case of non-convergence, alternative structures are used.

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TABLE 4.3.1.1
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ADVERSE EVENTS, TEAE 1
 SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	84 (13.5)	607	76 (12.5)	0.96 [0.69, 1.33]	0.97 [0.69, 1.24]	-0.45 [-4.13, 3.23]	0.8101
Attack 2	194	14 (7.2)	980	113 (11.5)	1.75 [0.99, 3.09]	1.66 [0.79, 2.53]	4.64 [0.63, 8.65]	0.0547
Attack 3	187	15 (8.0)	922	103 (11.2)	1.32 [0.78, 2.23]	1.28 [0.67, 1.89]	2.50 [-1.86, 6.87]	0.2983
Attack 4	173	21 (12.1)	869	117 (13.5)	1.09 [0.68, 1.77]	1.08 [0.63, 1.53]	1.03 [-4.31, 6.38]	0.7115
Overall effect	1177	134 (11.4)	1195	326 (27.3)	1.25 [0.99, 1.57]	1.22 [0.97, 1.47]	2.20 [0.03, 4.37]	0.0605
Interaction								0.3381

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.1.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ADVERSE EVENTS, SEVERE TEAE 1

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	1 (0.2)	607	0	0.51 [0.05, 5.69]	0.51 [-0.72, 1.75]	-0.16 [-0.70, 0.39]	0.5866
Attack 2	194	0	980	1 (0.1)	0.40 [0.04, 4.43]	0.40 [-0.56, 1.36]	-0.31 [-1.35, 0.73]	0.4536
Attack 3	187	0	922	1 (0.1)	0.41 [0.04, 4.54]	0.41 [-0.57, 1.39]	-0.31 [-1.39, 0.77]	0.4658
Attack 4	173	0	869	1 (0.1)	0.40 [0.04, 4.46]	0.40 [-0.56, 1.37]	-0.34 [-1.51, 0.82]	0.4569
Overall effect	1177	1 (0.1)	1195	3 (0.3)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack

interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.1.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ADVERSE EVENTS, SERIOUS TEAE 1

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	1 (0.2)	607	0	0.51 [0.05, 5.69]	0.51 [-0.72, 1.75]	-0.16 [-0.70, 0.39]	0.5866
Attack 2	194	0	980	2 (0.2)	0.60 [0.06, 5.80]	0.60 [-0.76, 1.95]	-0.20 [-1.26, 0.85]	0.6571
Attack 3	187	0	922	2 (0.2)	0.61 [0.06, 5.95]	0.61 [-0.77, 2.00]	-0.20 [-1.30, 0.90]	0.6725
Attack 4	173	0	869	2 (0.2)	0.60 [0.06, 5.85]	0.60 [-0.76, 1.97]	-0.23 [-1.41, 0.96]	0.6612
Overall effect	1177	1 (0.1)	1195	6 (0.5)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.1.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

ANALYSIS OF ADVERSE EVENTS, TEAE 1 LEADING TO DISCONTINUATION

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	1 (0.2)	607	1 (0.2)	0.28 [0.03, 2.43]	0.28 [-0.32, 0.89]	-0.22 [-0.56, 0.13]	0.2498
Attack 2	194	1 (0.5)	980	2 (0.2)	0.24 [0.05, 1.06]	0.24 [-0.12, 0.60]	-0.57 [-1.38, 0.24]	0.0603
Attack 3	187	0	922	1 (0.1)	5.36 [0.10, 277.84]	5.35 [-15.75, 26.44]	0.26 [-0.09, 0.61]	0.4043
Attack 4	173	0	869	3 (0.3)	5.62 [0.38, 82.37]	5.59 [-9.40, 20.58]	0.58 [0.06, 1.09]	0.2072
Overall effect	1177	2 (0.2)	1195	7 (0.6)	1.20 [0.39, 3.65]	1.20 [-0.13, 2.53]	0.04 [-0.19, 0.27]	0.7533
Interaction								0.2118

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.1.5
 ATOGEPANT (STUDY M24-305) - (DATE OF DATACUT: 07072025)
 ANALYSIS OF ADVERSE EVENTS, TEAE 1 LEADING TO DEATH
 SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	0	607	0	1.03 [0.06, 16.51]	1.03 [-1.82, 3.88]	0.00 [-0.44, 0.45]	0.9844
Attack 2	194	0	980	0	0.20 [0.01, 3.21]	0.20 [-0.35, 0.75]	-0.41 [-1.43, 0.61]	0.2548
Attack 3	187	0	922	0	0.20 [0.01, 3.29]	0.20 [-0.36, 0.77]	-0.42 [-1.48, 0.64]	0.2621
Attack 4	173	0	869	0	0.20 [0.01, 3.23]	0.20 [-0.36, 0.76]	-0.46 [-1.60, 0.69]	0.2567
Overall effect	1177	0 (0.0)	1195	0 (0.0)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.2.1

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

SENSITIVITY ANALYSIS OF ADVERSE EVENTS EXCLUDING DISEASE-RELATED EVENTS, TEAE 1

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	81 (13.0)	607	75 (12.4)	0.98 [0.71, 1.37]	0.99 [0.70, 1.27]	-0.19 [-3.83, 3.45]	0.9185
Attack 2	194	14 (7.2)	980	112 (11.4)	1.73 [0.98, 3.07]	1.65 [0.78, 2.52]	4.53 [0.53, 8.54]	0.0594
Attack 3	187	15 (8.0)	922	102 (11.1)	1.31 [0.77, 2.21]	1.27 [0.67, 1.88]	2.41 [-1.95, 6.76]	0.3148
Attack 4	173	21 (12.1)	869	117 (13.5)	1.09 [0.67, 1.76]	1.08 [0.63, 1.53]	0.98 [-4.38, 6.34]	0.7251
Overall effect	1177	131 (11.1)	1195	325 (27.2)	1.25 [0.99, 1.58]	1.22 [0.96, 1.47]	2.18 [0.02, 4.35]	0.0613
Interaction								0.3938

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.2.2

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

SENSITIVITY ANALYSIS OF ADVERSE EVENTS EXCLUDING DISEASE-RELATED EVENTS, SEVERE TEAE 1

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	0	607	0	1.03 [0.06, 16.51]	1.03 [-1.82, 3.88]	0.00 [-0.44, 0.45]	0.9844
Attack 2	194	0	980	0	0.20 [0.01, 3.21]	0.20 [-0.35, 0.75]	-0.41 [-1.43, 0.61]	0.2548
Attack 3	187	0	922	1 (0.1)	0.41 [0.04, 4.54]	0.41 [-0.57, 1.39]	-0.31 [-1.39, 0.77]	0.4658
Attack 4	173	0	869	1 (0.1)	0.40 [0.04, 4.46]	0.40 [-0.56, 1.37]	-0.34 [-1.51, 0.82]	0.4569
Overall effect	1177	0 (0.0)	1195	2 (0.2)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.2.3

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

SENSITIVITY ANALYSIS OF ADVERSE EVENTS EXCLUDING DISEASE-RELATED EVENTS, SERIOUS TEAE 1

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	1 (0.2)	607	0	0.51 [0.05, 5.69]	0.51 [-0.72, 1.75]	-0.16 [-0.70, 0.39]	0.5866
Attack 2	194	0	980	1 (0.1)	0.40 [0.04, 4.43]	0.40 [-0.56, 1.36]	-0.31 [-1.35, 0.73]	0.4536
Attack 3	187	0	922	2 (0.2)	0.61 [0.06, 5.95]	0.61 [-0.77, 2.00]	-0.20 [-1.30, 0.90]	0.6725
Attack 4	173	0	869	2 (0.2)	0.60 [0.06, 5.85]	0.60 [-0.76, 1.97]	-0.23 [-1.41, 0.96]	0.6612
Overall effect	1177	1 (0.1)	1195	5 (0.4)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.2.4

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

SENSITIVITY ANALYSIS OF ADVERSE EVENTS EXCLUDING DISEASE-RELATED EVENTS, TEAE 1 LEADING TO DISCONTINUATION

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	0	607	1 (0.2)	2.06 [0.19, 22.81]	2.06 [-2.88, 6.99]	0.17 [-0.38, 0.72]	0.5561
Attack 2	194	1 (0.5)	980	2 (0.2)	0.33 [0.04, 2.52]	0.33 [-0.34, 1.00]	-0.51 [-1.78, 0.75]	0.2848
Attack 3	187	0	922	1 (0.1)	0.41 [0.04, 4.54]	0.41 [-0.57, 1.39]	-0.31 [-1.39, 0.77]	0.4658
Attack 4	173	0	869	3 (0.3)	0.80 [0.09, 7.26]	0.80 [-0.96, 2.56]	-0.11 [-1.32, 1.09]	0.8450
Overall effect	1177	1 (0.1)	1195	7 (0.6)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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TABLE 4.3.2.5

ATOGEPA NT (STUDY M24-305) - (DATE OF DATACUT: 07072025)

SENSITIVITY ANALYSIS OF ADVERSE EVENTS EXCLUDING DISEASE-RELATED EVENTS, TEAE 1 LEADING TO DEATH

SAF1 ANALYSIS SET

Attack	----- Placebo -----		----- Atogepant -----		----- Atogepant vs. Placebo -----			p-value
	N	n (%)	N	n (%)	OR [95% CI]	RR [95% CI]	RD [95% CI]	
Attack 1	624	0	607	0	1.03 [0.06, 16.51]	1.03 [-1.82, 3.88]	0.00 [-0.44, 0.45]	0.9844
Attack 2	194	0	980	0	0.20 [0.01, 3.21]	0.20 [-0.35, 0.75]	-0.41 [-1.43, 0.61]	0.2548
Attack 3	187	0	922	0	0.20 [0.01, 3.29]	0.20 [-0.36, 0.77]	-0.42 [-1.48, 0.64]	0.2621
Attack 4	173	0	869	0	0.20 [0.01, 3.23]	0.20 [-0.36, 0.76]	-0.46 [-1.60, 0.69]	0.2567
Overall effect	1177	0 (0.0)	1195	0 (0.0)	-	-	-	

The SAF1 population of the DB phase includes all subjects who received at least 1 dose of study drug during the DB treatment period (based on the planned treatment sequence).

A TEAE is defined as an adverse event with onset on or after the first dose of study drug and occurring within 30 days after the most recent administration of study drug.

A TEAE 1 is defined as TEAE that is assigned to a DB dose of a study drug.

CI=Confidence interval, DB=Double blind, n=Number of subjects with events, N=Number of subjects who received treatment for a specific attack; for the overall assessment, subjects who received treatment for at least one attack, OR=Odds ratio, RD=Risk difference, RR=Relative risk, SAF1=Safety analysis set of the DB phase, TEAE=Treatment emergent adverse event

Percentages are calculated as 100 x (n/N).

A generalized linear mixed model (GLMM) with logit-link was applied to analyze the data on four migraine attacks. The model includes treatment group, attack, treatment-by-attack interaction. The model uses an unstructured covariance structure, in case of non-convergence, alternative structures and models are used. The overall effect is computed across attacks.

The interaction p-value refers to the treatment-by-attack interaction. The p-value is derived from the model and thus matches the OR. RR and RD with CIs were derived using the delta method.

For OR and RR, values < 1 indicate a favor of Atogepant. For RD, values < 0 indicate a favor of Atogepant.

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