

Supplementary Materials

Atogepant for the Preventive Treatment of Migraine in Japanese Participants: A Phase 3, Open-Label, 52-Week Extension Study

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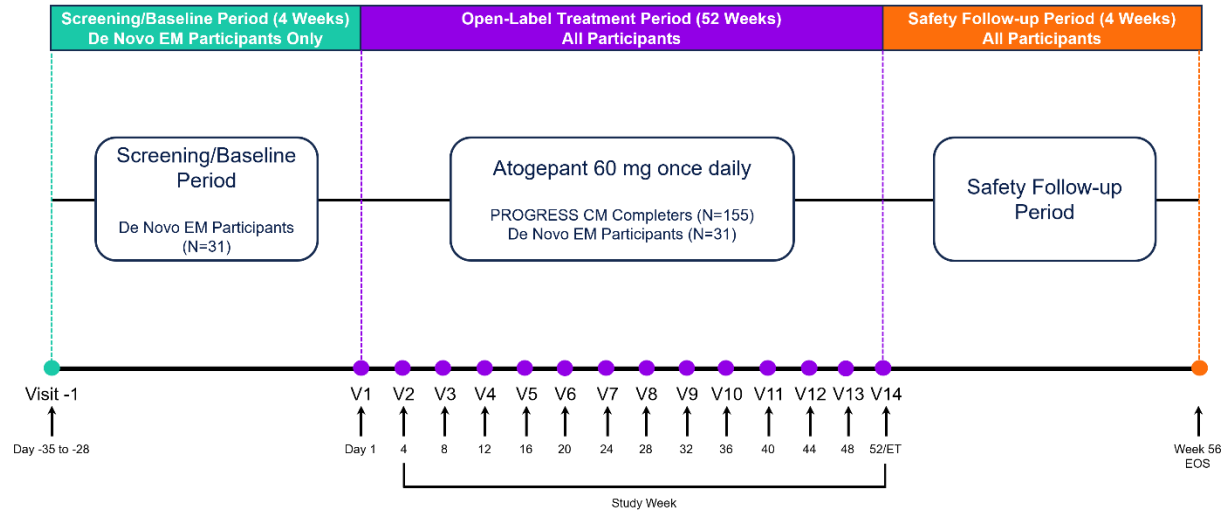
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Supplemental Figure 1: Study Design



CM, chronic migraine; EM, episodic migraine; EOS, end of study; ET, end of treatment; V, visit.

Supplemental Table 1: Hepatic-Related Laboratory Parameters (Safety Population)

Parameter		PROGRESS CM Completers (N = 155) n/N1 (%)	De Novo EM Participants (N = 31) n/N1 (%)	Total (N = 186) n/N1 (%)
ALT (U/L)	≥1 x ULN	19/155 (12.3)	4/31 (12.9)	23/186 (12.4)
	≥1.5 x ULN	13/155 (8.4)	2/31 (6.5)	15/186 (8.1)
	≥2 x ULN	10/155 (6.5)	1/31 (3.2)	11/186 (5.9)
	≥3 x ULN	9/155 (5.8)	0	9/186 (4.8)
	≥5 x ULN	5 /155(3.2)	0	5/186 (2.7)
	≥10 x ULN	1/155 (0.6)	0	1/186 (0.5)
	≥20 x ULN	1/155 (0.6)	0	1/186 (0.5)
AST (U/L)	≥1 x ULN	15/155 (9.7)	3/31 (9.7)	18/186 (9.7)
	≥1.5 x ULN	11/155 (7.1)	1/31 (3.2)	12/186 (6.5)
	≥2 x ULN	7/155 (4.5)	1/31 (3.2)	8/186 (4.3)
	≥3 x ULN	5/155 (3.2)	0	5/186 (2.7)
	≥5 x ULN	2/155 (1.3)	0	2/186 (1.1)
	≥10 x ULN	1/155 (0.6)	0	1/186 (0.5)
	≥20 x ULN	1/155 (0.6)	0	1/186 (0.5)
ALT or AST (U/L)	≥1 x ULN	20/155 (12.9)	4/31 (12.9)	24/186 (12.9)
	≥1.5 x ULN	15/155 (9.7)	2/31 (6.5)	17/186 (9.1)
	≥2 x ULN	10/155 (6.5)	1/31 (3.2)	11/186 (5.9)
	≥3 x ULN	9/155 (3.2)	0	9/186 (4.8)
	≥5 x ULN	5/155 (3.2)	0	5/186 (2.7)
	≥10 x ULN	1/155 (0.6)	0	1/186 (0.5)
	≥20 x ULN	1/155 (0.6)	0	1/186 (0.5)
TBL (umol/L)	≥1 x ULN	12/155 (7.7)	4/31 (12.9)	16/186 (8.6)
	≥1.5 x ULN	1/155 (0.6)	0	1/186 (0.5)
	≥2 x ULN	0	0	0
ALP (U/L)	≥1 x ULN	11/155 (7.1)	3/31 (9.7)	14/186 (7.5)
	≥1.5 x ULN	2/155 (1.3)	0	2/186 (1.1)
	≥2 x ULN	2/155 (1.3)	0	2/186 (1.1)
	≥3 x ULN	1/155 (0.6)	0	1/186 (0.5)
	≥5 x ULN	0	0	0
Concurrent Elevations	ALT or AST ≥3 x ULN and TBL ≥1.5 x ULN	1/155 (0.6)	0	1/186 (0.5)
	ALT or AST ≥3 x ULN and TBL ≥2 x ULN	0	0	0
Potential Hy's Law	ALT or AST ≥3 x ULN and TBL	0	0	0

	≥2 x ULN and ALP <2 x ULN			
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ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; n, number of participants in a specific category; N, number of participants in the safety population; N1, number of participants with non-missing non-potentially clinically significant baseline value and at least 1 postbaseline assessment; TBL, total bilirubin; ULN, upper limit of normal.

Supplemental Table 2: Change from Baseline in MIDAS Total Score (mITT Population). For the PROGRESS CM completers, baseline was the baseline value in the lead-in study. For the de novo EM participants, baseline was assessed during the last 28 days of the screening/baseline period.

Total Score	PROGRESS CM Completers (N=150)		De Novo EM Participants (N=30)	
	Mean (SD)	n	Mean (SD)	n
Baseline	32.6 (35.3)	150	23.8 (30.6)	30
Change from Baseline				
Week 12	-13.4 (40.2)	150	-13.8 (24.1)	30
Week 24	-11.7 (37.6)	139	-16.9 (29.8)	29
Week 36	-11.4 (44.4)	133	-18.0 (30.5)	28
Week 48	-12.9 (38.4)	131	-18.9 (29.2)	28
Week 52	-7.9 (43.5)	130	-19.1 (28.9)	28

CM, chronic migraine; EM, episodic migraine; MIDAS, Migraine Disability Assessment; mITT, modified intent-to-treat; SD, standard deviation.