ONLINE SUPPLEMENTAL MATERIAL

Sustained efficacy of eptinezumab in participants with migraine for whom prior preventive treatments failed and who self-reported psychiatric comorbidities: Post hoc analysis of the placebo-controlled DELIVER trial

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Table S1. Ethics committees and institutional review boards that approved the DELIVER clinical trial protocol

Country/Site	Central ethics committee or institutional review board
Belgium	Ethics Committee Research UZ/KU Leuven Leuven
Bulgaria	Republic of Bulgaria Ministry of Health, Ethics Committee for Clinical Trials Sofia
Czech Republic	Ethics Committee of the Institute of Clinical and Experimental Medicine and Thomayer Hospital Prague
Denmark	The Committees on Health Research Ethics for the Capital Region Hovedstaden
Finland	National Committee on Medical Research Ethics Helsinki
France	CPP South East VI Clermont-Ferrand
Georgia	
GE0001	Local Ethics Committee of Ltd Aversi Clinic Tbilisi
GE0002	Local Ethics Committee of Ltd Archangel St. Michael Multiprofile Clinical Hospital Tbilisi
GE0003	Local Ethics Committee of Ltd Malkhaz Katsiashvili Multiprofile Emergency Medicine Center Tbilisi
GE0004	Local Ethics Committee of Ltd Medi Club Georgia Grodno
GE0005	Local Ethics Committee of Ltd Acad. Fridon Todua Medical Center – Ltd Research Institute of Clinical Medicine Tbilisi
GE0006	Local Ethics Committee of Ltd Pineo Medical Ecosystem Tbilisi
GE0007	Local Ethics Committee of JSC Jerarsi Tbilisi
GE0008	Local Ethics Committee was held at Ltd Multiprofile Clinic Consilium Medulla Tbilisi
GE0009	Local Ethics Committee of Ltd Simon Khechinashvili University Clinic Tbilisi
GE0010	Local Ethics Committee of Ltd “Israel-Georgian Medical Research Clinic Helsicore” Tbilisi
Germany	Ethics Committee at the State Medical Association in Hessen Frankfurt
Hungary	Medical Research Council, Ethics Committee for Clinical Pharmacology Budapest

Italy	IRCCS San Raffaele Roma Scientific Institute for Hospitalization and Healthcare Ethics Committee Roma
Poland	Bioethics Committee at the District Medical Council of the Greater Poland Medical Chamber Poznan Poznan
Russian Federation	
RU0001	Independent Interdisciplinary Committee on Ethical Expert Review for Clinical Studies Moscow
RU0002	MEDIS Local Ethics Committee Nizhny Novgorod
RU0003	Local Ethics Committee at the Republican Clinical Neurology Centre Kazan
RU0004	Local Ethics Committee at the Federal State Budgetary Educational Institution of Higher Education Kazan State Medical University of the Ministry of Health of the Russian Federation Kazan
RU0005	Local Ethics Committee No. 1 Central Clinical Hospital RZhD-Meditsina Moscow
RU0006	Local Ethics Committee at the Federal State Budgetary Educational Institution of Higher Education Academician I.P. Pavlov First Saint Petersburg State Medical University of the Ministry of Health of the Russian Federation Saint Petersburg
Slovakia	Independent Ethics Committee of BBSK Banská Bystrica
Spain	Regional Drug Research Ethics Committee for the Community of Madrid Madrid
Sweden	Swedish Ethical Review Authority Uppsala
United Kingdom	North West – Haydock Research Ethics Committee Manchester
United States	Advarra IRB Columbia, Maryland

As previously reported in Pozo-Rosich P, et al. 2024 (doi:10.1007/s40120-023-00575-5).

Table S2. Baseline characteristics and treatment assignment by analysis population and migraine type

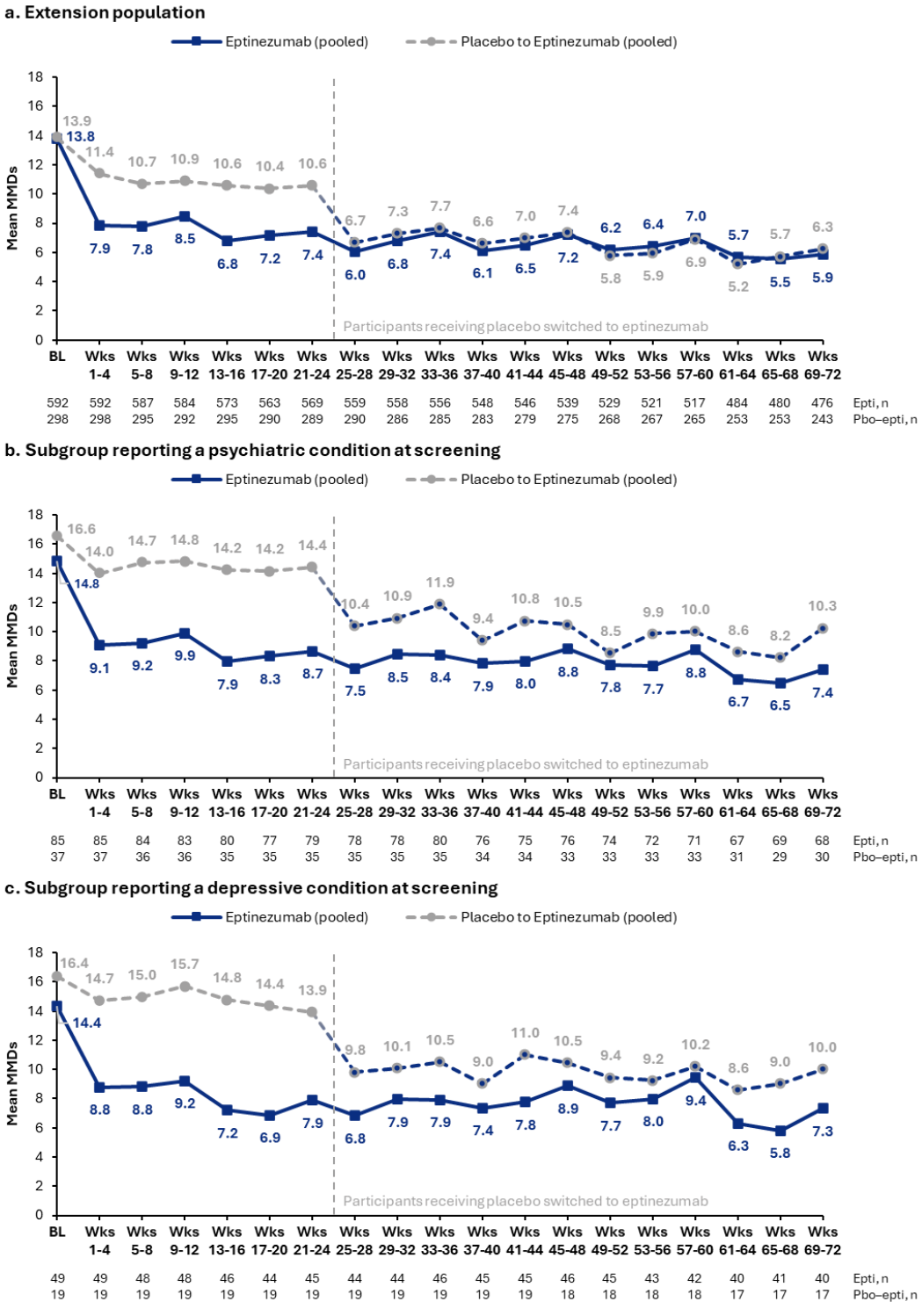
	Total efficacy population					
	Subgroup with psychiatric conditions (n=122)			**Subgroup with depressive conditions** (n=68)		
	EM subset (n=49)	**CM subset** (n=73)	**HFEM+CM subset** (n=109)	**EM subset** (n=30)	**CM subset** (n=38)	**HFEM+CM subset** (n=59)
Treatment group, n (%)						
Eptinezumab 100 mg	19 (38.8%)	25 (34.2%)	38 (34.9%)	10 (33.3%)	13 (34.2%)	19 (32.2%)
Eptinezumab 300 mg	18 (36.7%)	23 (31.5%)	36 (33.0%)	13 (43.3%)	13 (34.2%)	22 (37.3%)
Placebo	12 (24.5%)	25 (34.2%)	35 (32.1%)	22 (73.3%)	19 (50.0%)	18 (30.5%)
	Extension population					
	Subgroup with psychiatric conditions (n=115)			**Subgroup with depressive conditions** (n=65)		
	EM subset (n=47)	**CM subset** (n=68)	**HFEM+CM subset** (n=103)	**EM subset** (n=28)	**CM subset** (n=37)	**HFEM+CM subset** (n=57)
Treatment group, n (%)						
Eptinezumab 100 mg	18 (38.3%)	23 (33.8%)	35 (34.0%)	9 (32.1%)	12 (32.4%)	17 (29.8%)
Eptinezumab 300 mg	17 (36.2%)	22 (32.4%)	35 (34.0%)	12 (42.9%)	13 (35.1%)	22 (38.6%)
Placebo	12 (25.5%)	23 (33.8%)	33 (32.0%)	7 (25.0%)	12 (32.4%)	18 (31.6%)
Age						
Mean (SD)	45.9 (7.0)	45.4 (11.9)	45.5 (10.4)	46.4 (5.5)	45.2 (12.3)	45.7 (10.6)
Median (Q1, Q3)	46 (41, 49.5)	46 (37, 53)	46 (38.5, 52)	46.5 (42, 49)	48 (36, 54)	47 (38, 53)
Sex, n (%)						
Male	6 (12.8%)	7 (10.3%)	11 (10.7%)	3 (10.7%)	2 (5.4%)	4 (7.0%)
Female	41 (87.2%)	61 (89.7%)	92 (89.3%)	25 (89.3%)	35 (94.6%)	53 (93.0%)
# Prior treatment failures, n (%)						
>2	10 (21.3%)	24 (35.3%)	32 (31.1%)	4 (14.3%)	13 (35.1%)	16 (28.1%)
2	37 (78.7%)	44 (64.7%)	71 (68.9%)	24 (85.7%)	24 (64.9%)	41 (71.9%)
Years living with migraine						
Mean (SD)	19.4 (10.6)	20.2 (13.7)	20.1 (12.8)	19.8 (11.3)	20.9 (12.5)	21.1 (12.3)
Median (Q1, Q3)	18 (9.5, 25.5)	17 (10.8, 28)	18 (10.5, 27)	19 (9.8, 25.2)	20 (11, 28)	22 (11, 28)

	Extension population					
	Subgroup with psychiatric conditions (n=115)			**Subgroup with depressive conditions** (n=65)		
	EM subset (n=47)	**CM subset** (n=68)	**HFEM+CM subset** (n=103)	**EM subset** (n=28)	**CM subset** (n=37)	**HFEM+CM subset** (n=57)
MOH diagnosis, n (%)						
No	46 (97.9%)	55 (80.9%)	89 (86.4%)	28 (100%)	31 (83.8%)	51 (89.5%)
Yes	1 (2.1%)	13 (19.1%)	14 (13.6%)	0	6 (16.2%)	6 (10.5%)
Migraine type, n (%)						
CM	–	68 (100%)	68 (66.0%)	–	37 (100%)	37 (64.9%)
EM	47 (100%)	–	35 (34.0%)	28 (100%)	–	20 (35.1%)
MMDs during baseline						
Mean (SD)	9.8 (2.6)	19.0 (4.1)	16.3 (5.2)	10.0 (2.8)	18.8 (4.3)	16.2 (5.1)
Median (Q1, Q3)	10 (7.9, 12.2)	18 (16, 21.8)	16 (13, 20.7)	10 (7.7, 13)	18.7 (15, 21.8)	15 (13, 20.7)

The extension population included all randomized participants who received study treatment, had a valid baseline assessment of MMDs, and ≥1 valid assessment of MMDs in the extension period. The subgroup with psychiatric conditions included participants who self-reported the presence of ≥1 psychiatric condition at the screening visit. The subgroup with depressive conditions included participants for whom ≥1 self-reported psychiatric condition at the screening visit was depression or depressive symptoms. EM was defined as ≤14 MHDs and ≥4 MMDs at baseline, CM was defined as >14 MHDs and ≥8 MMDs at baseline, and HFEM+CM was defined as ≥8 MMDs at baseline.

CM, chronic migraine; EM, episodic migraine, HFEM, high-frequency episodic migraine; MMDs, monthly migraine days; MOH, medication-overuse headache; Q1, 1st quartile (25th percentile); Q3, 3rd quartile (75th percentile); SD, standard deviation.

Figure S1. Mean MMDs during the extension period in the (a) extension population, (b) extension subgroup reporting a psychiatric condition at screening, and (c) extension subgroup reporting a depressive condition at screening.



The extension population included all randomized participants who received study treatment, had a valid baseline assessment of MMDs, and ≥1 valid assessment of MMDs in the extension period. The subgroup with psychiatric conditions included participants in the extension population who self-reported the presence of ≥1 psychiatric

condition at the screening visit. The subgroup with depressive conditions included participants in the extension population for whom ≥1 self-reported psychiatric condition at the screening visit was depression or depressive symptoms.

The eptinezumab (pooled) group included all participants randomized to either eptinezumab 100 mg or 300 mg during the placebo-controlled period; the placebo group included all participants randomized to placebo for the placebo-controlled period then eptinezumab 100 mg or 300 mg for the extension period.

BL, baseline; Epti, eptinezumab (pooled treatment arm); MMDs, monthly migraine days; Pbo–epti, placebo-to-eptinezumab (pooled treatment arm); Wks, Weeks.