#EPO-420

Efficacy and Safety of Erenumab in Patients with Episodic Migraine in Indian population: India Sub-set Analysis of Global EMPOwER Study

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2021 EAN Annual Meeting, June 19-22 | virtual

AMGEN NOVARTIS

Disclosures

Sneha Thakur and Anup Thorat— employees in Novartis.

Funding source: This study is supported by Novartis Pharma AG, Basel, Switzerland. Erenumab is co-developed by Amgen and Novartis.

Acknowledgment: Medical writing support and design support by Mool Tatvam Consulting LLP, Mumbai, India.
Dr. Osvaldo Carlos Bruera, Norma Haydee Deri, Dr. Eduardo Daniel Doctorovich, Dr. Bibiana Saravia, Dr. Carlos Federico Buonanotte, Dr. Maria Teresa Goicochea, Dr. Maria de Lourdes Figuerola, Dr. Thomas Iype, Dr. Rahul Chakor, Prof. Srinivasa Rangasetty, Dr. Manoj Hunnur, Dr. Mukesh Sharma, Dr. Praveen Chander,Dr. Prafulla Shembalkar, Dr. Charulata Sankhla, Dr. Gagandeep Singh, Dr. Ish Anand, Dr. Priyanka Vikas Kashyap, Dr. Boby Varkey Maramattom, Dr. Rahul Baviskar, Dr. Pradeep Kumar Vayyattu Govindankutty, Dr. Suresh Kumar, Dr. M. V. Padma Srivastava, Dr. Jayantee Kalita, Dr. Saroja A O, Dr. Suresh K, Dr. Madhusudhan BK, Dr. Vijaya Pamidimukkala, Dr. Amit Yeole, Dr. Hrishikesh Kumar, Byung Kun Kim, Manho Kim, Dr. KyungMi Oh, Soo Jin Cho, Jeong Wook Park, Jae-Moon Kim, Joung Ho Rha, Seung-han Lee, Heui-soo Moon, Eung Gyu Kim, Miji Lee, Min Kyung Chu, Dr. Taghrid El Hajj, Dr. Achraf Makki, Dr. Souheil Gebeily, Dr. Shawkat Beayni, Dr. Salim Atrouni, Dr. Naji Riachi, Dr. Aline Mourad, Prof. Tai Mei-Ling Sharon, Dr. Mohd Sufian Adenan, Dr. Sapiah Sapuan, Dr. Irene Looi, Dr. Rabani Remli, Carlos Martinez Manzanera, Dr. Luis Roberta Partida Medina, Dr. Jose Oropeza de Alba, Dr. Jose Alfonso Meza Medina, Martha Bolanos, Greg David Dayrit, Dr. Paul Matthew Pasco, Artemio Jr Roxas, Dr. Yasmin Idu Jion, Prof. Lo Yew Long, Shuu-Jiun Wang, Lu-An Chen, Long-Sun Ro, Chun-Pai Yang, Yung Chu Hsu, Kao Chang Lin, Po Jen Wang, Kang Hsu Lin, Surat Tanprawate, Prof. Thanin Asawavichienjinda, Col. Chesda Udommongkol, Dr. Tasanee Tantirittisak, Assoc prof. Somsak Tiamkao, Tai Tran, Le Van Thinh, Subhayan Mondal- Principal Biostatistician, Novartis, Nadia Tenenbaum- Senior Clinical Development Medical Director, Novartis.

INTRODUCTION

- In India, the overall prevalence is not well known. A study conducted in Karnataka estimated age-standardized 1-year prevalence of 25.2% and prevalence was found to be greater among females and in rural areas (Kulkarni et al 2014).
- Available prophylactic therapies are associated with variable efficacy, and/or tolerability issues leading to treatment discontinuation, which highlights a significant unmet need in migraine prevention.
- Calcitonin gene related peptide (CGRP) a neuropeptide, has been shown to play a key role in migraine pathophysiology.
- Erenumab is a fully human monoclonal antibody targeting the receptor for CGRP, and thus is an attractive target for migraine-specific prophylactic therapy.

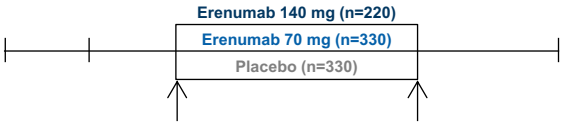
OBJECTIVE

- EMPOwER (NCT03333109) is a 12-week, double-blind, randomized study to compare the efficacy and safety of once monthly erenumab (70 mg and 140 mg SC) against placebo in adult EM patients from Asia, the Middle East and Latin America. This is an India sub-analysis of the Global study.

METHODOLOGY

- This study used a single-cohort, 3-treatment arm, randomized, double-blind study design in adult subjects with EM.
- 351 Indian subjects were randomized to receive either erenumab or placebo in a 2:3:3 ratio (erenumab 140 mg: erenumab 70 mg: placebo) **(Figure 1).**
- Screening period: 2 weeks followed by 4 week baseline.
- After randomization, visits occurred at 4 week intervals until week 12.
- A safety follow-up visit occurred 12 weeks later, at week 24 (end of study).
- Primary endpoint was change from baseline in monthly migraine days (MMD). Secondary endpoints assessed ≥50% reduction in MMD, changes in headache impact test (HIT-6) and safety.

Figure 1: Study schema



Screen	Baseline	DBTP	Follow-Up
2 weeks	4 weeks	12 weeks	12 weeks

DBTP: Double-blind treatment period.

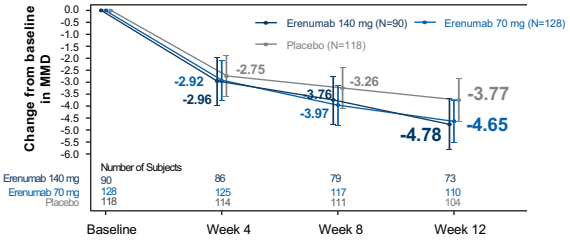
RESULTS

- Demographics by subject and by treatment are illustrated in **Table 1.**
- Change in MMD was numerically greater in the erenumab group. At week 12, the difference in adjusted means (95% CI; p-value) in MMD was − 0.88 (− 2.16, 0.39; p = 0.174) days for erenumab 70 mg vs. placebo and – 1.01 (– 2.42, 0.41; p = 0.164) days for erenumab 140 mg vs. placebo **(Figure 2).**

Table 1: Demographic characteristics at baseline

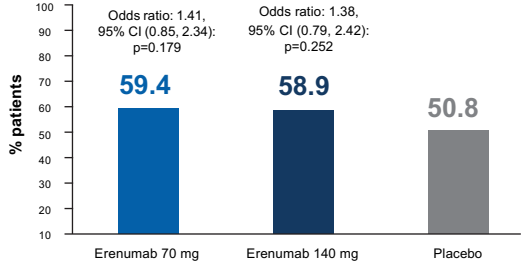
Characteristic	Erenumab 140 mg N= 94	Erenumab 70 mg N= 133	Placebo N= 124	All subjects N= 351
Age (years) Mean (SD)	35.4 (7.2)	34.9 (9.2)	35.3 (8.9)	35.1 (8.6)
Sex - n (%) Male	16 (17.0)	31 (23.3)	27 (21.8)	74 (21.1)
Female	78 (83.0)	102 (76.7)	97 (78.2)	277 (78.9)
Disease duration of migraine (years) Mean (SD)	6.66 (6.54)	6.76 (5.96)	6.87 (5.69)	6.77 (6.01)
Monthly migraine days Mean (SD)	8.34 (3.75)	7.69 (2.67)	7.56 (2.27)	7.82 (2.89)
Monthly headache days Mean (SD)	9.48 (4.67)	8.75 (2.88)	8.50 (2.55)	8.86 (3.37)
Monthly days of acute migraine specific medication Mean (SD)	0.10 (0.58)	0.20 (1.14)	0.20 (1.00)	0.17 (0.97)

Figure 2: Change from baseline in MMD



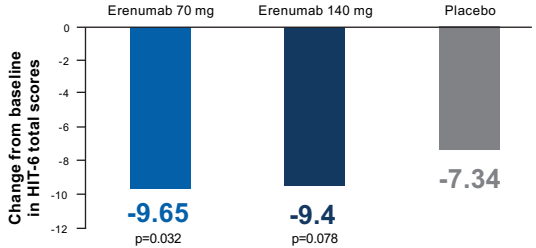
- Patients achieving ≥50% reduction in MMD was higher in erenumab 70 mg and 140 mg vs. placebo (59.4% and 58.9% vs. 50.8%; p vs. placebo: 0.179 [70 mg] and 0.252 [140 mg]) **(Figure 3).**

Figure 3: Proportion of patients with ≥50% reduction in MMD at week 12



- Change in HIT-6 score was -7.34 with placebo, -9.65 and -9.40 with erenumab 70 mg and 140 mg respectively (p vs. placebo: 0.032 [70 mg] and 0.078 [140 mg]) **(Figure 4).**

Figure 4: Change from baseline in HIT-6 total scores at week 12



- Overall safety profile of erenumab was comparable with placebo with no new safety signals **(Table 2).**
- Frequencies of the treatment-emergent adverse events (TEAEs) during the DBTP were comparable across the treatment groups with 22.7% in the erenumab 70 mg group, 24.5% in the erenumab 140 mg group, and 25.2.% in the placebo group.
- Treatment-related AEs were reported in 5.3%, 6.4%, and 5.7% of subjects from the erenumab 70 mg,140 mg and placebo groups, respectively.
- No deaths were reported during the study. No serious AEs were reported in the erenumab treated groups during the DBTP.
- No subjects discontinued the study treatment due to AEs in any of the treatment groups.

Table 2: Summary of TEAEs during DBTP

	Erenumab 140 mg N= 94	Erenumab 70 mg N= 132	Placebo N= 123	All subjects N= 349
Category	**All grades n (%)**			
Adverse events	23 (24.5)	30 (22.7)	31 (25.2)	84 (24.1)
Treatment-related	6 (6.4)	7 (5.3)	7 (5.7)	20 (5.7)
SAEs	0	0	1 (0.8)	1 (0.3)
Treatment-related	0	0	0	0
Deaths	0	0	0	0
AEs leading to study treatment discontinuation	0	0	0	0
AEs leading to dose interruption	0	0	1 (0.8)	1 (0.3)
AEs requiring additional therapy	20 (21.3)	25 (18.9)	22 (17.9)	67 (19.2)

Safety follow-up period:

- A total of 333 subjects entered the safety follow-up period.
- The overall proportion of subjects with AEs reported during the safety follow-up period were comparable between the erenumab groups and placebo group.
- The frequency of AEs were 4.9% in the erenumab 70 mg group, 6.6% in the erenumab 140 mg group, and 3.4% in the placebo group.

CONCLUSION

- While the study was not powered to evaluate the efficacy of erenumab in the Indian subpopulation, the efficacy and safety profile of erenumab in Indian patients showed improvement numerically for relevant endpoints versus placebo; thus consistent with the global EMPOwER study population.

MLR ID: 133192