



## Lilly Receives Positive CHMP Opinion for Emgality™ (galcanezumab) for the Prophylaxis of Migraine in Adults

September 21, 2018

INDIANAPOLIS, Sept. 21, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Emgality™ (galcanezumab) for the prophylaxis of migraine in adults who have at least four migraine days per month.

In June 2018, Lilly announced the intended brand name, Emgality™, was conditionally accepted by the U.S. Food and Drug Administration (FDA).

Emgality is a humanized monoclonal antibody specifically designed to bind to the calcitonin gene-related peptide (CGRP), blocking its function without interacting with the CGRP receptor. Emgality is an investigational, once-monthly, self-administered injection under evaluation for the prevention of migraine, with no titration needed.

This is the first regulatory step toward approval for Emgality in Europe. The CHMP positive opinion is now referred for final action to the European Commission, which grants approval in the European Union.

Migraine is a neurological disease characterized by recurrent episodes of severe headache accompanied by other symptoms including nausea, vomiting, sensitivity to light and sound, and changes in vision.<sup>1,2</sup>

"Migraine affects more than 100 million people globally, making it the third most prevalent disease in the world. Migraine can also have a significant impact on a person's ability to fully participate in their personal and professional life," said Gudarz Davar, M.D., vice president, Neurology Development, Lilly Bio-Medicines.<sup>1,2</sup> "If approved, we're very excited about the potential to offer Emgality as a new option for migraine prevention that could provide more migraine-free days to people living with this debilitating disease."

The CHMP positive opinion was based on Phase 3 data from two clinical trials in patients with episodic migraine (EVOLVE-1 and EVOLVE-2) and one Phase 3 clinical trial in patients with chronic migraine (REGAIN). In all three clinical trials (EVOLVE-1, EVOLVE-2 and REGAIN), Emgality reduced mean monthly migraine headache days in the first month and every following month in the treatment period compared to placebo.

In EVOLVE-1 and EVOLVE-2, which studied patients with episodic migraine, the majority of patients (~60%) treated with Emgality achieved at least a 50 percent reduction, on average, in monthly migraine headache days in any given month ( $p < 0.001$ ) compared to 38.6% and 36% of patients on placebo in EVOLVE-1 and EVOLVE-2, respectively. In these studies, more than one-third of patients achieved at least a 75 percent reduction, on average, in monthly migraine headache days in any given month ( $p < 0.001$ ) compared to 19.3% and 17.8% of patient on placebo in EVOLVE-1 and EVOLVE-2, respectively. One in 7 patients (15.6%) were migraine headache-free in any given month in EVOLVE-1, on average ( $p < 0.001$ ) compared to 6.2% of patients on placebo.

Emgality has been studied in more than 2,500 patients in clinical studies for migraine prevention. More than 1,400 patients were exposed to Emgality during the placebo-controlled Phase 3 studies, with less than 2.5% of patients discontinuing due to treatment-related adverse events.

The U.S. Food and Drug Administration (FDA) is currently reviewing Emgality for the preventive treatment of migraine in adults. A decision regarding approval is expected by the end of September 2018.

### About the EVOLVE-1 and EVOLVE-2 Studies

EVOLVE-1 and EVOLVE-2 are six-month, Phase 3, randomized, multicenter, double-blind, placebo-controlled trials that enrolled a total of 1,773 adult patients with episodic migraine (defined as 4 to 14 migraine headache days [MHDs] per month) with or without aura. In each trial, participants were randomized to once-monthly placebo, Emgality 120 mg after an initial loading dose of 240 mg or galcanezumab 240 mg. Patients with acute cardiovascular events and/or with serious cardiovascular risk were excluded. For each study the primary endpoint was the overall mean change from baseline in the number of monthly MHDs over months one to six in the intent-to-treat study population. Emgality was provided as a 120 mg injection self-administered once-monthly.

### About the REGAIN Study

REGAIN is a three-month, double-blind, placebo-controlled study that enrolled 1,113 adult patients with chronic migraine (defined as  $\geq 15$  MHDs per month with  $\geq 8$  MHDs per month). Participants were randomized to receive once-monthly placebo, Emgality 120 mg after an initial loading dose of 240 mg or galcanezumab 240 mg. A total of 15% of patients continued concomitant preventive treatments. Patients with acute cardiovascular events and/or serious cardiovascular risk were excluded. The primary endpoint was the overall mean change from baseline in the number of monthly MHDs over months one to three in the intent-to-treat study population. Emgality was provided as a 120 mg injection self-administered once-monthly.

### About Migraine

Migraine is a neurological disease characterized by recurrent episodes of severe headache accompanied by other symptoms including nausea, vomiting, sensitivity to light and sound, and changes in vision.<sup>1,2</sup> More than 100 million people globally have migraine, with three times more women affected by migraine compared to men.<sup>3,3</sup>

### About Emgality™

Emgality™ (galcanezumab) is an investigational monoclonal antibody specifically designed to bind to and inhibit the activity of calcitonin gene-related peptide (CGRP), which is believed to play a role in migraine. Emgality is also under investigation for the prevention of cluster headache.

## About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and [www.lilly.com/newsroom/social-channels](http://www.lilly.com/newsroom/social-channels). P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Emgality™ (galcanezumab) for the prevention of migraine in adults, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Emgality will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

<sup>1</sup> Steiner TJ et al. Migraine: the seventh disabling. *The Journal of Headache and Pain* 2013, 14:1.

<sup>2</sup> Pavone E et al. Patterns of triptans use: a study based on the records of a community pharmaceutical department. *Cephalalgia*. 2007;27(9):1000-4.

<sup>3</sup> Migraine facts. Migraine Research Foundation website. <http://migraineresearchfoundation.org/about-migraine/migraine-facts/>. Last accessed August 21, 2018.

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The Lilly logo is rendered in a vibrant red, cursive script. The letters are fluid and interconnected, with a classic, elegant feel. The 'L' is particularly large and prominent, leading into the 'i', 'l', 'l', 'e', 'y' which follow in a similar flowing style. The overall appearance is that of a handwritten signature or a stylized brand mark.

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