Lilly to Present New Data at AAN 2019 on Emgality® (galcanezumab-gnlm) and Lasmiditan Reinforcing Breadth of Headache Disorders Portfolio

May 2, 2019

- 19 abstracts to be presented, including Phase 3, eight-week data on Emgality for the preventive treatment of episodic cluster headache in adults, featured in a plenary presentation

- First-time presentation of lasmiditan clinical data on the onset of response for the acute treatment of migraine

INDIANAPOLIS, May 2, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it will present 19 scientific abstracts for Emgality® (galcanezumab-gnlm) and lasmiditan at the 71st Annual Meeting of the American Academy of Neurology (AAN) taking place in Philadelphia from May 4-10, 2019. Emgality (120 mg) is indicated for the preventive treatment of migraine, Emgality (300 mg) is an investigational drug for the preventive treatment of episodic cluster headache, and lasmiditan is an investigational drug for the acute treatment of migraine, all in adults.

The data to be presented further establish Lilly's breadth of research and clinical programs aimed at developing innovative approaches to the treatment of debilitating and difficult-to-treat headache disorders.

"Migraine and episodic cluster headache are extremely debilitating disorders, and we are committed to finding good treatment options for those living with these neurologic diseases," said Gudarz Davar, M.D., vice president, Neurology Development, Lilly Bio-Medicines. "The data presented at AAN reflect Lilly's deep commitment and expertise in searching for and finding solutions for some of today's toughest challenges in migraine and disabling headache disorders," said Dr. Davar.

In a plenary session on May 7, 2019, Lilly will highlight Phase 3, eight-week findings for Emgality as an investigational preventive treatment for episodic cluster headache in adults. On May 6, 2019, Lilly will also present analyses from two Phase 3 studies (EVOLVE-1 & EVOLVE-2) evaluating Emgality in a subgroup of adults living with episodic migraine, by low- versus high-frequency of migraine headache days.

Lilly will also share new data for lasmiditan, including details on the onset of efficacy, in a platform presentation on May 6, 2019, and in a poster presentation based on clinical data from the Phase 3 GLADIATOR long-term extension study. Lasmiditan is an oral, centrally-penetrant, selective serotonin 5-HT_{1F} agonist that is structurally and mechanistically distinct from other approved migraine therapies and lacks vasoconstrictive activity. It is the first and only molecule in the "-ditan" class under evaluation by the U.S. Food and Drug Administration (FDA) for the acute treatment of migraine in adults. If approved, it could represent the first significant innovation for the acute pharmacological treatment of migraine in more than two decades.

Data disclosures, as well as the dates and times of the data sessions, are highlighted below.

Emgality (galcanezumab-gnlm) Presentations:

Sunday, May 5, 2019:

- **P1.10-001: Galcanezumab Significantly Reduced Health Care Resource Utilization and Acute Medication Use in Patients with Chronic Migraine: Findings from a Phase 3, Randomized, Double-Blind, Placebo-Controlled and Open-Label Extension**
  - Session information: Headache Clinical Trials I, 11:30 AM - 6:30 PM EST
  - Presenter: Joshua Tobin, M.D., neurologist, 21st Century Neurology, clinical associate professor, University of Arizona College of Medicine, Phoenix, AZ
- **P1.10-003: Patient Gains in Daily Functioning and Reductions in Disability with Galcanezumab among Patients with Episodic and Chronic Migraine**
  - Session information: Headache Clinical Trials I, 11:30 AM - 6:30 PM EST
  - Presenter: Linda Wietecha, BSN, MS, clinical research advisor, associate launch leader, Eli Lilly and Company, Indianapolis, IN
- **P1.10-010: Evaluation of Cardiovascular Risks in Adult Patients with Episodic or Chronic Migraine Treated with Galcanezumab: Data From Three Phase 3, Randomized, Double-Blind, Placebo-Controlled Studies**
  - Session information: Headache Clinical Trials I, 11:30 AM - 6:30 PM EST
  - Presenter: Noah Rosen, M.D., FAHS, program director, Northwell Health Headache Center, Great Neck, NY, associate professor, Donald and Barbara Zucker School of Medicine, Hofstra Northwell, Hempstead, NY
- **P1.10-017: Immunogenicity Assessment from Phase 3 Galcanezumab Trials in Patients with Episodic or Chronic Migraine**
  - Session information: Headache Clinical Trials I, 11:30 AM - 6:30 PM EST

- Presenter: Kavita Kalidas, M.D., assistant professor, director, Department of Neurology, University of South Florida Health, Morsani College of Medicine, Tampa, FL

Monday, May 6, 2019:

- **S17.003: Phase 3 Studies (EVOLVE-1 & EVOLVE-2) of Galcanezumab in Episodic Migraine: Subgroup Analyses of Efficacy by Low- Versus High-Frequency of Migraine Headache Days**
  - Session information: Headache: Clinical Trials I, 1:22 PM - 1:33 PM EST
  - Presenter: Steve Silberstein, M.D., FACP, professor, Sidney Kimmel Medical College, Thomas Jefferson University, director, Headache Center, Jefferson University Hospital, Philadelphia, PA
- **P2.10-010: One-Year Treatment with Galcanezumab in Patients with Chronic Migraine: Results from the Open-Label Phase of the REGAIN Study**
  - Session information: Headache Clinical Trials II, 11:30 AM - 6:30 PM EST
  - Presenter: Lily Li, M.D., clinical research scientist, Eli Lilly and Company, Indianapolis, IN
- **P2.10-014: Safety Data from Phase 3 Clinical Studies Comparing Galcanezumab and Placebo in Patients with Episodic and Chronic Migraine**
  - Session information: Headache Clinical Trials II, 11:30 AM - 6:30 PM EST
  - Presenter: Tina Oakes, Ph.D., clinical research advisor, Eli Lilly and Company, Indianapolis, IN
- **P2.10-021: Effect of Age on Efficacy and Safety of Galcanezumab Treatment in Adult Patients with Migraine**
  - Session information: Headache Clinical Trials II, 11:30 AM - 6:30 PM EST
  - Presenter: Phebe Kemmer, Ph.D., research scientist, Eli Lilly and Company, Indianapolis, IN

Tuesday, May 7, 2019:

- **Plen02.004: A Placebo-Controlled Study of Galcanezumab in Patients with Episodic Cluster Headache: Results from the 8-Week Double-Blind Treatment Phase**
  - Session information: Clinical Trials Plenary Session, 9:15 AM - 11:30 AM EST
  - Presenter: David Dodick, M.D., FAHS, FRCP, FACP, professor, Department of Neurology, Mayo Clinic Alix School of Medicine, medical director, Headache Program, Mayo Clinic, Phoenix, AZ

Wednesday, May 8, 2019:

- **P4.10-015: Effect of Galcanezumab on Severity of Headache and Associated Symptoms of Migraine in Phase 3 Trials in Patients with Episodic or Chronic Migraine**
  - Session information: Migraine II, 11:30 AM - 6:30 PM EST
  - Presenter: Michael Ament, M.D., neurologist, Ament Headache Center, Denver, CO

Thursday, May 9, 2019:

- **P5.10-011: Features of Episodic Cluster Headache in the Real-World Setting: Clinical Characteristics from a Large, Multi-National, Cross-Sectional Survey**
  - Session information: Headache, 11:30 AM - 6:30 PM EST
  - Presenter: Jim Martinez, M.D., senior medical director, Eli Lilly and Company, Indianapolis, IN
- **P5.10-015: Acute and Preventive Treatment Patterns in Episodic Cluster Headache: Findings from the United States, United Kingdom and Germany**
  - Session information: Headache, 11:30 AM - 6:30 PM EST
  - Presenter: Russ Nichols, PharmD, clinical research scientist, Eli Lilly and Company, Indianapolis, IN
- **P5.10-019: Healthcare Resource Use and Humanistic Burden Associated with Attack Frequency in Episodic Cluster Headache**
  - Session information: Headache, 11:30 AM - 6:30 PM EST
  - Presenter: Jeffrey Scott Andrews, Pharm.D., senior research scientist, Eli Lilly and Company, Indianapolis, IN

Lasmiditan Presentations:

Sunday, May 5, 2019:

- **P1.10-009: Safety Findings from the Phase 3 Studies (SAMURAI, SPARTAN) of Lasmiditan for Acute Treatment of Migraine**
  - Session information: Headache Clinical Trials I, 11:30 AM - 6:30 PM EST
  - Presenter: John Krege, M.D., medical fellow, Eli Lilly and Company, Indianapolis, IN
- **P1.10-021: Long-term Safety and Efficacy of Lasmiditan for Acute Treatment of Migraine Over a One-Year Period: Interim Results of an Open-Label Phase 3 Study (GLADIATOR)**
  - Session information: Headache Clinical Trials I, 11:30 AM - 6:30 PM EST

- Presenter: Jan Brandes, M.D., MS, FAAN, assistant clinical professor, Department of Neurology, Vanderbilt University School of Medicine, Nashville, TN

Monday, May 6, 2019:

- **S17.007: Onset of Efficacy Following Oral Treatment with Lasmiditan for the Acute Treatment of Migraine**
  - Session information: Headache: Clinical Trials I, 2:06 PM - 2:17 PM EST
  - Presenter: Erin Doty, senior medical advisor, Eli Lilly and Company, Indianapolis, IN
- **P2.10-011: How Adverse Events Are Collected and Reported: Differences Between Randomized Phase 2 and Phase 3 Clinical Trials for Lasmiditan**
  - Session information: Headache Clinical Trials II, 11:30 AM - 6:30 PM EST
  - Presenter: John Krege, M.D., medical fellow, Eli Lilly and Company, Indianapolis, IN

Wednesday, May 8, 2019:

- **P4.10-017: Acute Anti-Migraine Prescription Varies According to Baseline Cardiovascular Risk and Clinical Characteristics: A Real-World Evidence Study**
  - Session information: Migraine II, 11:30 AM - 6:30 PM EST
  - Presenter: Hu Li, M.D., Ph.D. principal research scientist, Eli Lilly and Company, Indianapolis, IN
- **P4.10-022: Response to Lasmiditan for Acute Treatment of Migraine Based on Prior Response to Triptan Therapy**
  - Session information: Migraine II, 11:30 AM - 6:30 PM EST
  - Presenter: Kerry Knievel, D.O., neurologist, Barrow Neurological Institute, Phoenix, AZ

Emgality is a monoclonal antibody that selectively binds to calcitonin gene-related peptide (CGRP) which was approved by the FDA in September 2018 for the preventive treatment of migraine in adults and in Europe for the prophylactic treatment of migraine in adults who have at least four migraine days per month. Emgality is also currently under Priority Review by the FDA as an investigational drug for the preventive treatment of episodic cluster headache in adults.

Emgality represents the first of three investigational treatments in development as part of Lilly's overall pain portfolio. The portfolio also includes lasmiditan, an investigational drug for the acute treatment of migraine in adults and tanezumab, developed in partnership with Pfizer, which is being investigated for the treatment of osteoarthritis pain, chronic low back pain and cancer pain in adults.

Indications and Usage for Emgality
Emgality (galcanezumab-gnlm) 120 mg injection is a monoclonal antibody that selectively binds to calcitonin gene-related peptide (CGRP) and is indicated for the preventive treatment of migraine in adults.

Important Safety Information for Emgality

Contraindications
Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Warnings and Precautions
Hypersensitivity Reactions
Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

Adverse Reactions
The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see Full Prescribing Information, including Patient Information, for Emgality. See Instructions for Use included with the pen and prefilled syringe.

GZ HCP ISI 27SEP2018

About Cluster Headache
Cluster headache is a disabling primary headache disorder characterized by severe pain with recurrent 'attacks' of intense headaches which occur in cyclical patterns on one side of the head, frequently associated with pain behind or around one eye, restlessness and agitation.[1] During a cluster period, attacks can last 15 to 180 minutes and occur from once every other day to eight times a day for more than half of the time during a cluster period.[1] Episodic cluster headache is the most common form of the condition, affecting 85 to 90 percent of people with the disorder.[1] In episodic cluster headache, attacks occur in series lasting for weeks or months (so-called cluster periods) separated by remission periods of at least three months.[1]

About Lasmiditan
Lasmiditan is an investigational, oral, first-in-class molecule under evaluation for the acute treatment of migraine in adults. Lasmiditan selectively targets 5-HT_{1F} receptors expressed in the trigeminal pathway and has been designed for the acute treatment of migraine without the vasoconstrictor activity associated with some migraine therapies.

About Lilly's Commitment to Headache Disorders
For over 25 years, Lilly has been committed to helping people affected by headache disorders, investigating more than a dozen different compounds for the treatment of migraine and cluster headache. These research programs have accelerated our understanding of these diseases and furthered

the advancement of our comprehensive late-stage development programs studying galcanezumab-gnlm, approved by the U.S. Food and Drug Administration for the preventive treatment of migraine in adults and currently under Priority Review for episodic cluster headache in adults, and lasmiditan, an investigational drug currently under review by the U.S. Food and Drug Administration for the acute treatment of migraine with or without aura in adults. Our goal is to apply our combined clinical, academic and professional experience to build a research portfolio that delivers comprehensive solutions and addresses the needs of people affected by these disabling neurologic diseases.

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 and 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-gnlm) as a preventive treatment for patients with migraine and potential treatment for patients with episodic cluster headache; lasmiditan as a potential acute treatment for patients with migraine; and tanezumab, being developed in partnership with Pfizer, as a potential treatment for patients with osteoarthritis, chronic low back pain and cancer pain 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 additional regulatory approvals or be commercially successful or that lasmiditan or tanezumab will receive regulatory approval. 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.

References:

1. Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

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