Lilly Reveals Critical Barriers to Optimal Migraine Care and Insights From Novel Clinical and Patient-Centric Real-World Evidence, Supporting Lilly's Preventive and Acute Treatment Portfolio at AHS 2021

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- Nearly half of people with migraine hesitated to seek care, choosing self-management and out of concern their disease would not be taken seriously, based on new findings from OVERCOME (U.S.), the largest population-based study of its kind

- Emgality® (galcanezumab-gnlm) achieved greater adherence and persistence compared to oral standard of care (non-CGRP mAb) preventive migraine treatments and the auto-injector pen profile had a greater probability of patient preference compared to Aimovig® (erenumab) and AJOVY® (fremanezumab) auto-injector profiles in real-world analyses

- REYVOW® (lasmiditan) C-V 100 mg and 200 mg delivered greater odds of achieving two hour pain freedom and two hour pain relief compared to Nurtec® (rimegepant) or UBRELVY® (ubrogepant) in the first network pairwise comparison meta-analysis comprehensive of all Phase 2 and 3 studies to date

INDIANAPOLIS, June 3, 2021 /PRNewswire/ -- To improve the understanding and advance the treatment of migraine, Eli Lilly and Company (NYSE: LLY) presented data on unmet needs in migraine from the OVERCOME (U.S.) study and on its portfolio of migraine medicines during the American Headache Society (AHS) 2021 Virtual Annual Scientific Meeting, June 3-6. New findings from OVERCOME (U.S.) revealed the top six reasons why people hesitate to seek migraine care.[1] Real-world data insights revealed greater adherence and persistence for Emgality® (galcanezumab-gnlm), a calcitonin gene-related peptide monoclonal antibody (CGRP mAb), compared to oral standard of care (non-CGRP mAb) preventive migraine treatments in a healthcare claims study and greater probability of patient preference for the Emgality auto-injector profile compared to Aimovig® (erenumab) and AJOVY® (fremanezumab) device characteristics in a survey.[2,3] In the first pairwise comparison network meta-analysis (NMA) for the acute treatment of migraine comprehensive of the totality of literature available to date, people taking 100 mg and 200 mg doses of REYVOW® (lasmiditan) C-V had greater odds of early onset of efficacy compared to those taking Nurtec® (rimegepant) or UBRELVY® (ubrogepant).[4]

"People with migraine want and need rapid and complete freedom from migraine. It's important they find treatment options that work for them so they can stay on them, rather than be dissatisfied or worse, give up hope and not even seek treatment. These new insights reveal barriers to optimal care and reinforce the robust profiles of Emgality and REYVOW as preventive and acute migraine medicines, respectively," said Ilya Yuffa, senior vice president and president, Lilly Bio-Medicines. "We hope to inspire people with migraine and healthcare providers to talk about the impact this debilitating neurologic disease has on daily life. People should expect more, and get more, from their treatments on the path to freedom from debilitating migraine pain."

OVERCOME Study Reveals Nearly Half of Respondents Hesitate to Seek Migraine Care

In the most recent results from the OVERCOME (U.S.) study, nearly half (45%, n=17,951/39,494) of participants hesitated to seek migraine care and of those, 42% (7,495/17,951; 31 respondents could not recall) did not seek migraine care in the preceding 12 months. Of the 7,495, nearly half (45%) reported that they want to take care of their symptoms on their own, and more than one-third (35%) were concerned their migraine would not be taken seriously. Other reasons cited included not believing their migraine attacks were serious or painful enough (29%), financial considerations (29%) and insurance access, and reimbursement (21%). 42% of those who did not seek migraine care in the preceding 12 months experienced at least moderate disability, as measured by Migraine Disability Assessment (MIDAS), which assesses the impact of headache attacks on daily activities in school, work, at home or socially across three months. Due to the debilitating impact of migraine attacks, advocacy organizations encourage people with a mild or above MIDAS score to see their healthcare provider.[1]

"OVERCOME, the largest population-based study of its kind, provides crucial insights to improve migraine care," said Robert E. Shapiro, M.D., Department of Neurological Sciences, Larner College of Medicine, University of Vermont, and scientific advisor to the OVERCOME study. "Given that nearly half of survey respondents hesitated to seek migraine care, we urgently need to understand the bases for these barriers and promote more effective dialogue between healthcare providers and people with migraine to improve their health outcomes."

Emgality, and Other CGRP mAbs, Helped More Patients Stay on Treatment Compared to Oral Standard of Care (Non-CGRP mAb) Preventive Migraine Treatments

Lilly's analysis is the first study of U.S. healthcare administrative claims to evaluate adherence and persistence of the CGRP mAb class of migraine preventive medicines compared to the oral standard of care (non-CGRP mAb) for migraine preventive treatments over six months. After matching on the propensity to initiate a CGRP mAb treatment (n=2,986 for each group), more people taking Emgality were adherent (more than half, 51.2%) compared to those taking oral standard of care (non-CGRP mAb) treatments (less than a third, 27.6%) at six months. After propensity matching (n=7,867 for each group), more people taking CGRP mAb treatments were adherent (nearly half, 49.0%) compared to those taking oral standard of care (non-CGRP mAb) preventive treatments (less than a third, 27.8%) at six months.[2] Adherence to index medication was assessed as proportion of days covered (PDC) >80% over a six-month post-index period.

In the six-month study with a maximum 60-day gap between prescription fills, three out of four patients (74.3%) taking Emgality filled four or more prescriptions and persistently used treatment for 148.9 days or nearly five months. By comparison, 28.7% of people taking oral standard of care

(non-CGRP mAb) treatments filled four or more prescriptions and they persisted on treatment for 92.7 days or approximately three months. N=2,986 for each group. Two out of three patients (66.2%) taking a CGRP mAb filled their fourth or more prescription and persistently used treatment for 142.6 days compared to less than one out of three (29%) of those taking oral standard of care (non-CGRP mAb) preventive treatments with a persistence of 93 days (n=7,867 for each group). Persistence was measured by number of days of continuous therapy from index until the end of the six-month post-index period, allowing for a maximum gap between fills of 60 days.[2]

After propensity matching Emgality and oral standard of care (non-CGRP mAb) patients (n=2,986 for each group), patients taking oral standard of care (non-CGRP mAb) treatment were nearly 2.5 times more likely to discontinue treatment than those taking Emgality (61.2% compared to 25.6%). Similarly, after propensity matching oral standard of care (non-CGRP mAb) and CGRP mAb patients (n=7,867 for each group), patients taking oral standard of care (non-CGRP mAb) preventive migraine treatments were twice as likely to discontinue treatment than those taking CGRP mAb treatments (61.3% compared to 31%).[2]

Emgality Auto-Injector Characteristics Had a Higher Probability to be Preferred by Patients Compared to Device Characteristics of Other Self-Injectable Preventive Migraine Treatments

1,067 adults residing in the United States, the United Kingdom, and Germany with moderate to severe episodic migraine or chronic migraine and experience with migraine preventive treatments within 5 years, completed a stated-preference web-based survey using a discrete choice experiment (DCE). Experience with clinician-prescribed preventive treatments for migraine within the previous 5 years was required and people who were treatment-naïve were excluded. On average, participants were 41.2 years old, had lived with migraine for 17.4 years, and they had previously used on average 3.5 preventive treatments. Half (50.4%) had experience using self-injectables, and more than half (54.8%) had low or no fear of needles. More than two-thirds (72.0%) of the participants had severe or very severe disability based on MIDAS.[3]

Self-injectable treatments were predicted to be preferred over oral treatments in nearly nine out of ten (86.3%) choices made by participants. Preferences for two hypothetical injectable treatments were primarily driven by shorter injection duration, an auto-retracting needle, and longer outside-of-refrigerator storage. A profile comparable to the Emgality device had the highest likelihood of being preferred by nearly half of participants (45.6%) compared to a device profile comparable to Aimovig and AJOVY (29.4% and 25%, respectively).[3]

A DCE is an established preference elicitation method that is used to understand the effect of changes in key treatment attributes on patients' preferences. Participants repeatedly chose their preferred treatment among three hypothetical preventive treatment options for migraine characterized by the same attributes and varying levels of each: two CGRP-targeting mAb treatments administered using auto-injectors and a daily oral treatment by completing 15 DCE choice tasks. The three treatment options were described by varying levels of seven attributes, identified from literature review and focus groups and that were introduced to participants by a video: dosing schedule, storage requirements, base and pinching requirements, injection steps, injection duration, needle removal, and dose confirmation.

This study did not evaluate patient use of the devices nor did it compare the clinical safety and efficacy of these treatments.

For additional information, please see the Patient Preferences for Self-Injectable Preventive Treatments for Migraine study details below.

"Our device was designed with patients in mind, and we are pleased to see that for people with migraine, there's a greater probability that they prefer the Emgality auto-injector profile over those of the Aimovig and AJOVY devices, using discrete choice experiment methods. We are also thrilled that nearly 75% of people on Emgality consistently filled their prescriptions compared to the less than 30% of those taking non-CGRP mAb (oral standard of care) preventive migraine medications at the fourth fill. In the absence of head-to-head studies, these real-world insights about Emgality are especially valuable given high discontinuation rates for people taking non-CGRP mAb treatments," said Antje Tockhorn-Heidenreich, senior research scientist, Global Patient Outcomes and Real World Evidence, Eli Lilly and Company.

REYVOW (100 mg and 200 mg) Demonstrated Greater Odds of Achieving Two Hour Pain Freedom and Two Hour Pain Relief Compared to Nurtec and UBRELVY in Network Meta-Analysis (NMA)

In the first NMA of its kind to include the totality of Phase 2 and 3 studies (n=13,514) available to date and to measure rapid efficacy at two hour pain freedom, two hour pain relief and one hour pain relief for all Phase 3 doses of REYVOW, Nurtec and UBRELVY, REYVOW 100 mg and 200 mg had greater odds for achieving pain freedom at two hours and pain relief at two hours compared to all doses of Nurtec and UBRELVY (statistically significant for majority of pairwise comparisons). People taking REYVOW 100 mg and 200 mg had greater odds of achieving pain relief at one hour compared to Nurtec 75 mg ODT and UBRELVY 50 mg. There were no published data on Nurtec 75 mg tablet and UBRELVY 25 mg and 100 mg for this endpoint. REYVOW 50 mg had comparable efficacy to the doses of Nurtec and UBRELVY.[4]

Pairwise treatment comparisons*	REYVOW 200 mg Odds ratio (95% credible interval)	REYVOW 100 mg Odds ratio (95% credible interval)	REYVOW 50 mg Odds ratio (95% credible interval)
Pain freedom at two hours			
REYVOW vs. Nurtec 75 mg	1.80 (1.49–2.16)	1.39 (1.15–1.67)	1.12 (0.87–1.42)
REYVOW vs. UBRELVY 25 mg	1.88 (1.44–2.45)	1.46 (1.11–1.89)	1.17 (0.86–1.58)
REYVOW vs. UBRELVY 50 mg	1.83 (1.46–2.27)	1.42 (1.13–1.76)	1.14 (0.86–1.48)
REYVOW vs. UBRELVY 100 mg	1.60 (1.21–2.08)	1.23 (0.93–1.61)	0.99 (0.72–1.35)
Pain relief at two hours			
REYVOW vs. Nurtec 75 mg	1.27 (1.05–1.53)	1.31 (1.09–1.58)	0.93 (0.74–1.16)
REYVOW vs. UBRELVY 25 mg	1.47 (1.13–1.90)	1.52 (1.17–1.97)	1.08 (0.81–1.43)
REYVOW vs. UBRELVY 50 mg	1.34 (1.08–1.68)	1.39 (1.12–1.74)	0.99 (0.76–1.27)
REYVOW vs. UBRELVY 100 mg	1.32 (1.02–1.71)	1.37 (1.05–1.77)	0.97 (0.73–1.30)
Pain relief at one hour			
REYVOW vs. Nurtec 75 mg	1.54 (1.18–2.01)	1.40 (1.07–1.82)	0.97 (0.72–1.32)
REYVOW vs. UBRELVY 50 mg	1.54 (1.22–1.95)	1.39 (1.10–1.76)	0.97 (0.74–1.28)

*Pairwise treatment comparisons – results from Bayesian fixed-effect NMA. Adjusted by baseline risk for pain freedom at 2 hours.

In the very early-onset exploration sensitivity analysis, REYVOW 200 mg had higher odds of achieving pain relief at 30 minutes compared to Nurtec 75 mg ODT and UBRELVY 50 mg. REYVOW 100 mg and 200 mg had higher odds of achieving pain freedom at one hour compared to UBRELVY 50 mg. There were no published data on Nurtec 75 mg (tablet and ODT) or UBRELVY 25 mg and 100 mg for this endpoint.[4]

Pairwise comparisons were evaluated in accordance with published guidelines.[5] Robustness of the results was investigated assessing the model's convergence and goodness of fit, and through sensitivity analyses, including looking at 1) only Phase 3 trials, 2) both Nurtec formulations (tablet and ODT), and 3) very early-onset including pain relief at 30 minutes and pain freedom at one hour.[4]

"We must address barriers to migraine care and inspire people to talk with healthcare providers about their treatment goals and the impact migraine has on their lives. It is so important that people find migraine medications that work for them; and we are excited to present new insights about migraine, Emgality, and REYVOW. We encourage everyone to expect more, and get more, from their preventive and acute migraine treatments, and to know that freedom from this disabling pain is possible," said Michael Cobas Meyer, M.D., vice president, global medical affairs, Lilly Bio-Medicines.

About the Studies

- **Reasons for Hesitating to Consult for Migraine Care: Results of the OVERCOME (U.S.) Study**
  A pooled analysis of the 2018 and 2019 cohorts of the **O**bser**v**ational Survey of the **E**pidemiology, T**r**eatment and **C**are **o**f **M**igrain**e** (OVERCOME) study evaluated whether 39,494 U.S. respondents hesitated to consult for migraine care and the reasons why. Comparisons were made between groups on variables including socio-demographics, migraine diagnosis, number of monthly headache days, sensitivity to light and sound and nausea, and self-reported outcomes on severity of disability among others.[1]

  The OVERCOME study is a multi-cohort, cross-sectional and longitudinal, prospective web-based patient survey designed to follow U.S. population samples with migraine for up to two years following their enrollment. This research aims to further understand the unmet needs of those with migraine by assessing the burden of migraine experienced by people living with the disease, identify barriers to the appropriate treatment of migraine, and assess how the introduction of novel treatment options may influence delivery of migraine care and outcomes.[1]

- **Adherence and Persistence Associated with Calcitonin Gene-Related Peptide (CGRP) Monoclonal Antibodies (mAbs) Compared to Oral Standard of Care (non-CGRP mAb) Migraine Preventive Treatments Among Adult Patients with Migraine**
  Retrospective observational cohort study using U.S. healthcare administrative claims from the IBM MarketScan Database between May 1, 2017, and December 30, 2019, adherence and persistence rates were evaluated for 12,681 adult patients with migraine initiating treatment with CGRP mAbs (Emgality, Aimovig or AJOVY), 3,253 patients with Emgality and 21,474 patients prescribed oral standard of care (non-CGRP mAbs) (antidepressants, beta-blockers, anticonvulsants) or neurotoxin. This included people with an ICHD-3 migraine diagnosis and patients had ≥1-year pre-index and ≥6 months post-index continuous enrollment. In order to control for bias, propensity score matching was implemented to match CGRP mAb patients to non-CGRP mAb patients, and Emgality patients to non-CGRP mAb patients.[2]

- **Patient Preferences for Self-Injectable Preventive Treatments for Migraine**
  The DCE was informed by a literature review and qualitative and quantitative research, including focus groups and pilot-testing the DCE, and questions fielded among participants did not include efficacy attributes. Preference was determined by relative attribute importance scores. Response data were analyzed using an error-component logit model (EC-MNL); EC-MNL estimates were used to calculate predictive choice probabilities of attributes profile comparable to Emgality, Aimovig and AJOVY. The number of studies included for each outcome was relatively small, which can lead to unstable models especially when using random effects models.[3]

- **Relative Efficacy of Lasmiditan versus Rimegepant and Ubrogepant as Acute Treatments of Migraine: Network Meta-Analysis (NMA) Findings on Early Onset of Efficacy**
  The NMA assessed 12 Phase 2-4 blinded, placebo-controlled, randomized controlled trials involving 13,514 adults with episodic or chronic migraine with or without aura. The analysis evaluated REYVOW 50 mg, 100 mg, and 200 mg, Nurtec 75 mg (tablet and ODT), and UBRELVY 25 mg, 50 mg, and 100 mg and early-onset efficacy endpoints included pain freedom at 2 hours and pain relief at 1 hour and 2 hours. Pairwise comparisons were reported as odds ratios with 95% credible intervals. Given the different mechanisms of action among treatments evaluated in the NMA, the safety profiles of each could not be compared quantitatively and discontinuation due to adverse events could not be analyzed.[4]

ABOUT REYVOW® (lasmiditan) TABLETS

REYVOW is a novel oral medication that strongly binds to 5-HT_{1F} receptors located both centrally and peripherally, which may play a role in migraine, a neurologic disease. REYVOW is approved for the acute treatment of migraine with or without aura in adults and is not indicated for the prevention of migraine. REYVOW, the first and only FDA-approved ditan, is brain-penetrant and presumably exerts its therapeutic effects by activating these receptors; however, the precise mechanism is unknown.

IMPORTANT SAFETY INFORMATION FOR REYVOW

WARNINGS AND PRECAUTIONS

Driving Impairment
REYVOW may cause significant driving impairment. In a driving study, administration of single 50 mg, 100 mg, or 200 mg doses of REYVOW significantly impaired subjects' ability to drive. Additionally, more sleepiness was reported at 8 hours following a single dose of REYVOW compared to placebo. Advise patients not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery, for at least 8 hours after each dose of REYVOW. Patients who cannot follow this advice should not take REYVOW. Prescribers and patients should be aware that patients may not be able to assess their own driving competence and the degree of impairment caused by REYVOW.

Central Nervous System Depression
REYVOW may cause central nervous system (CNS) depression, including dizziness and sedation. Because of the potential for REYVOW to cause sedation, other cognitive and/or neuropsychiatric adverse reactions, and driving impairment, REYVOW should be used with caution if used in combination with alcohol or other CNS depressants. Patients should be warned against driving and other activities requiring complete mental alertness for at least 8 hours after REYVOW is taken.

Serotonin Syndrome
In clinical trials, reactions consistent with serotonin syndrome were reported in patients treated with REYVOW who were not taking any other drugs associated with serotonin syndrome. Serotonin syndrome may also occur with REYVOW during coadministration with serotonergic drugs. Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular signs, and/or gastrointestinal signs and symptoms. The onset of symptoms usually occurs within minutes to hours of receiving a new or a greater dose of a serotonergic medication. Discontinue REYVOW if serotonin syndrome is suspected.

Medication Overuse Headache
Overuse of acute migraine drugs may lead to exacerbation of headache (i.e., medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

ADVERSE REACTIONS
The most common adverse reactions associated with REYVOW (≥2% and greater than placebo in clinical studies) were dizziness, fatigue, paresthesia, sedation, nausea and/or vomiting and muscle weakness.

ABUSE
REYVOW contains lasmiditan, a Schedule V controlled substance (C-V).
REYVOW has abuse potential. Evaluate patients for risk of drug abuse and observe them for signs of lasmiditan misuse or abuse.

See Full Prescribing Information **and** Medication Guide**.**
LM HCP ISI 28SEPT2020

About Emgality
Emgality is a monoclonal antibody that selectively binds to calcitonin gene-related peptide (CGRP) and was approved by the FDA in September 2018 for the preventive treatment of migraine in adults. Emgality is the only CGRP monoclonal antibody with response rates in the episodic migraine headache population on ≥50%, ≥75% and 100% reduction from baseline in monthly migraine headache days over Months 1 to 6 included in its Full Prescribing Information. In June 2019, Emgality was approved by the FDA for the treatment of episodic cluster headache in adults.

Indications and Usage for Emgality (galcanezumab-gnlm) 120 mg Injection
Emgality is a calcitonin gene-related peptide (CGRP) antagonist indicated in adults for the:

- preventive treatment of migraine
- treatment of episodic cluster headache

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, including dyspnea, urticaria, and rash, have occurred with Emgality in clinical studies and the postmarketing setting. Cases of anaphylaxis and angioedema have also been reported in the postmarketing setting. 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 device.

GZ HCP ISI 10DEC2019

About Migraine
Migraine is a severely disabling neurologic disease characterized by recurrent episodes of moderate to severe headache accompanied by other symptoms including nausea, sensitivity to light, and sensitivity to sound.[6,7] More than 30 million American adults have migraine, with three times more women than men affected by migraine.[8] Migraine is often incapacitating, leading to high personal, societal and economic burden. According to the Medical Expenditures Panel Survey, total annual healthcare costs associated with migraine are estimated to be as high as $56 billion in the United

States, yet it remains under-recognized and under-treated.[9]

About Lilly's Commitment to Headache Disorders
For more than 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 treatments for headache disorders including REYVOW, approved by the FDA for the acute treatment of migraine, with or without aura, in adults and Emgality, approved by the FDA for the preventive treatment of migraine and the treatment of episodic cluster headache. Our goal is to apply our combined clinical, academic and professional experience to build a research portfolio that delivers broad solutions and addresses the needs of people affected by these disabling neurologic diseases.

About Eli Lilly and Company
Lilly is a global health care leader that unites caring with discovery to create medicines that 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 lilly.com and lilly.com/newsroom.

Lilly Forward-Looking Statement
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about REYVOW (lasmiditan), as an acute treatment for patients with migraine, and Emgality (galcanezumab-gnlm), as a preventive treatment for patients with migraine and as a treatment for patients with episodic cluster headache, and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that future study results will be consistent with study findings to date, that REYVOW and/or Emgality will receive any additional regulatory approvals, or that REYVOW and/or Emgality will 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.
P-LLY

All product/company names shown herein are the trademarks of their respective owners.

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